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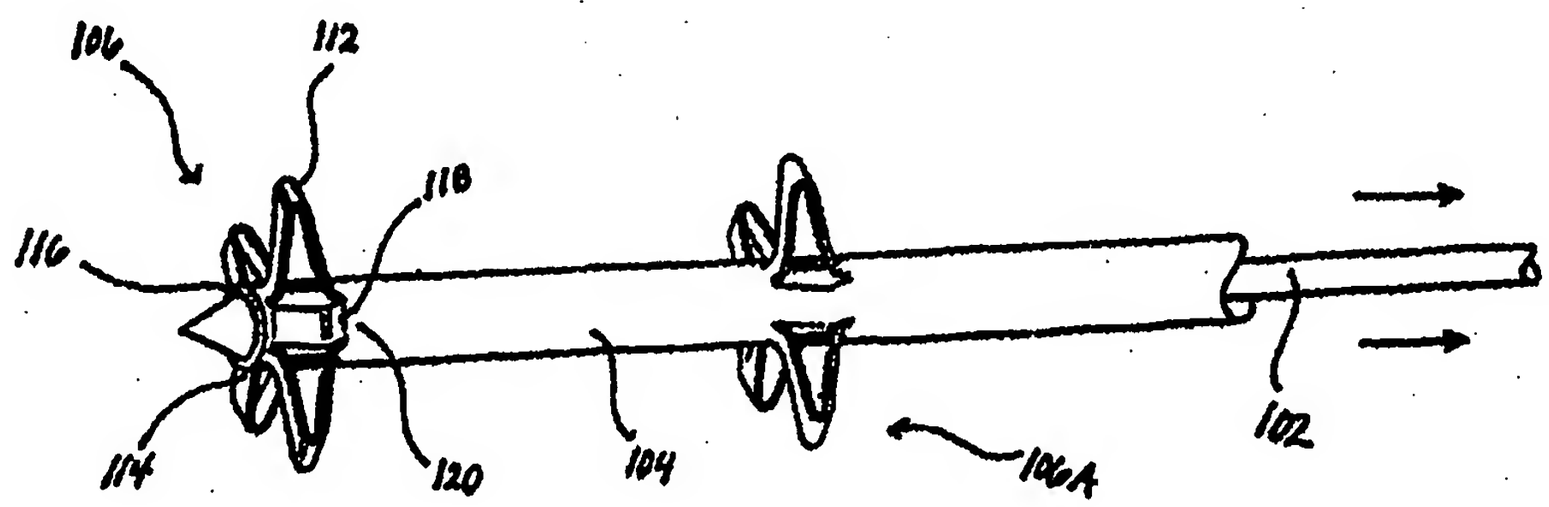

(57) Abstract

This invention is a trans–myocardial bypass device including retractors (R) used to engage, to support myocardial tissue, and mechanisms (100) for supporting coronary vessels so as to allow precise entry into a vessel lumen. Conduits (240) are provided having a configuration that permits positioning in a heart wall to place a coronary vessel in communication with a heart chamber.

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DEVICES AND METHODS FOR USE IN PERFORMING TRANSMYOCARDIAL CORONARY BYPASS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to treating heart disease, and more particularly systems, devices and methods for reestablishing or improving blood flow to the myocardium.

2. Description of the Background Art

Despite the considerable advances that have been realized in cardiology and cardiovascular surgery, heart disease remains the leading cause of death throughout much of the world. Coronary artery disease, or arteriosclerosis, is the single leading cause of death in the United States today. As a result, those in the cardiovascular field continue the search for new and improved treatments.

Coronary artery disease is currently treated by interventional procedures such as percutaneous transluminal coronary angioplasty (PTCA), atherectomy and intracoronary stenting, as well as surgical procedures including coronary artery bypass grafting (CABG). The goal of these procedures is to reestablish or improve blood flow through occluded (or partially occluded) coronary arteries, which is accomplished, for example, by enlarging the blood flow lumen of the artery or by forming a bypass that allows blood to circumvent the occlusion. What procedure(s) is used typically depends on the severity and location of the blockages. When successful, these procedures restore blood flow to myocardial tissue that had not been sufficiently perfused due to the occlusion.

Technological and procedural advances have improved the results obtained by the medical procedures now used to treat heart disease, and in particular coronary artery disease. There is, however, still much room for improvement. For that reason there remains a need in the art for new and improved systems, devices and methods for treating heart disease such as arteriosclerosis.

SUMMARY OF THE INVENTION

In one embodiment, the invention provides a device and method for engaging tissue of a coronary vessel or heart wall during a cardiovascular procedure. A

device constructed according to this embodiment includes first and second members coupled together so as to permit relative movement. A tissue engaging mechanism is coupled to the first and second members and moves between first and second positions. In the preferred embodiment, the first and second positions are collapsed and expanded orientations. The tissue engaging mechanism includes at least one tissue engaging member that contacts engage body tissue when in the expanded orientation.

A method carried out according to this embodiment includes steps of providing a tissue support device having a tissue engaging mechanism configured to assume an expanded, tissue supporting orientation, positioning the tissue support device through the wall of a patient's heart and locating the tissue engaging mechanism adjacent tissue, and placing the tissue engaging mechanism in the expanded, tissue supporting orientation in engagement with the tissue.

In another embodiment, the invention provides a device and method for supporting a wall of a vascular structure in order to access the lumen of the vascular structure. A device constructed according to this embodiment includes a support structure adapted to be positioned in the lumen of a vascular structure, the support structure comprising a plurality of support elements coupled together so as to be movable relative to each other. The support elements move relative to each other to move the support structure from a collapsed orientation to an expanded orientation in order to support a wall of a vascular structure, and are sized and configured so that when the support structure is in the expanded orientation the support elements engage the wall of the vascular structure to prevent the wall from collapsing.

Another device constructed according to this embodiment includes an introducer having a hollow interior and an elongated support member configured to be generally coiled when in an unbiased orientation and generally straight when in a biased orientation. The interior of the introducer is sized and configured to receive the elongated support member and hold the support member in the generally straight, biased orientation. The elongated support member is moved from the straight, biased orientation within the interior of the introducer to the coiled, unbiased orientation upon entering the interior of the vascular structure to support the vascular structure.

A method carried out according to this embodiment includes steps of positioning a support within an interior of a vascular structure such that the support contacts and supports a wall of the vascular structure, and introducing a medical device

into the interior of the vascular structure by passing the device through the wall of the vascular structure and through the support.

In another embodiment, the invention provides a device and method for stabilizing an area of a patient's heart adjacent a coronary vessel. A device constructed according to this embodiment includes a base configured to be positioned adjacent a coronary vessel of a patient's heart, the base having at least one opening for accessing the coronary vessel. At least one tissue engaging element is coupled to the base so as to be movable with respect to the base, the tissue engaging element having a portion configured to securely engage the wall of a patient's heart in order to stabilize the wall of the heart upon moving the tissue engaging element with respect to the base. An actuator is provided for imparting relative movement to the base and the tissue engaging element in order to stabilize the heart while accessing the coronary vessel through the opening in the base.

In yet another embodiment, the invention provides a conduit for placing a coronary vessel of a patient's heart in communication with a heart chamber. The conduit is in the form of a tubular element including first and second portions having different cross-sectional sizes and a bore defining a blood flow path. The cross-section of the first portion of the tubular element is larger than the cross-section of the second portion such that the tubular element is generally funnel-shaped, and the first and second portions of the tubular element are generally aligned so that the bore defines a generally straight blood flow path.

In still another embodiment, the invention provides a conduit for communicating a chamber of a patient's heart with a coronary vessel. The conduit is in the form of an expandable stent including first and second portions having different cross-sectional sizes when the stent is expanded. Each of the first and second portions of the stent includes strut members disposed along a first direction when the stent is unexpanded and along a second direction when the stent is expanded, the second direction being transverse to the first direction. The strut members of the first portion are longer than the strut members of the second portion so that the stent is generally funnel-shaped when expanded.

In another embodiment, the invention provides a conduit is in the form of an expandable tubular element having first and second portions with different cross-sectional sizes. This tubular element is preferably a coronary stent constructed so that the

first and second portions are disposed in an orientation that provides the stent with maximum radial strength when expanded.

In a final embodiment, the invention provides a conduit for placing a coronary vessel in communication with a heart chamber, the conduit including a vessel support mechanism configured to contact and support the vessel wall when the conduit is positioned in the heart wall.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood from the following detailed description of preferred embodiments thereof, taken in conjunction with the accompanying drawing figures, wherein:

Fig. 1 is a schematic view of a patient prepared to undergo a cardiovascular surgical procedure, the patient's heart being exposed via a retractor positioned in a thoracotomy formed in the patient's chest;

Fig. 2 is a perspective view of the heart shown in Fig. 1, wherein a portion of the heart wall is broken away for clarity;

Fig. 2A is an enlarged view of a portion of Fig. 2;

Figs. 3A-3B are perspective views showing a tissue engaging device constructed according to one embodiment of the invention, the device being shown in collapsed and expanded orientations, respectively;

Figs. 4A-4B are elevation views, in section, illustrating one preferred construction of a tissue engaging device according to the embodiment of Figs. 3A-3B, wherein the device is shown being used to engage the heart wall shown in Figs. 2-2A;

Figs. 5A-5B are elevation views, in section, illustrating another preferred construction of a tissue engaging device according to the embodiment of Figs. 3A-3B, wherein the device is shown being used to engage the heart wall shown in Figs. 2-2A;

Figs. 6A-6C are elevation views, in section, sequentially illustrating a vessel support device constructed according to another embodiment of the invention being used to support the wall of a vascular structure;

Fig. 7 is a perspective view of a vessel support device constructed according to an alternative embodiment of the invention, the device being shown positioned in the interior of a vascular structure;

Figs. 8A-8B are elevation views, in section, sequentially illustrating the device shown in Fig. 7 being used to support a coronary artery of the heart shown in Figs. 2-2A;

Fig. 9 is a perspective view of a vessel support device constructed according to another alternative embodiment of the invention, the device being shown positioned in the interior of a vascular structure;

Figs. 10A-10B are elevation views, in section, sequentially illustrating the device shown in Fig. 9 being used to support a coronary artery of the heart shown in Figs. 2-2A;

Figs. 11A-11B are plan views of a tissue engaging device constructed according to another embodiment of the invention, wherein the device is shown engaging the wall of the heart shown in Figs. 2-2A in non-retracting and retracting orientations, respectively;

Figs. 12A-12B are elevation views, in section, taken along lines A-A in Figs. 11A-11B;

Fig. 13 is an elevation view, in section, of an alternative tissue engaging device constructed according to the embodiment shown in Figs. 12A-12B;

Figs. 14A-14B are elevation views of a tapered balloon forming part of another embodiment of the invention, wherein the balloon is shown in its collapsed and expanded orientations, respectively;

Figs. 15A-15B are elevation views of an expandable conduit mounted on the tapered balloon shown in Figs. 14A-14B, the conduit being shown in its collapsed and expanded orientations, respectively;

Fig. 16 is an elevation view, in section, of a portion of a heart wall and coronary vessel in which the conduit shown in Fig. 15A-15B has been positioned;

Figs. 17A-17B are elevation views showing a conduit constructed according to still another embodiment of the invention, wherein the conduit has a cross-sectional size that varies over its length;

Fig. 18 is a perspective view of another embodiment of the invention providing a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel;

Figs. 19A-19C are schematic representations of a preferred application for the conduit shown in Fig. 18;

Fig. 20 is a perspective view of an alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel;

Fig. 21 is a perspective view of another alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel; and

Fig. 22 is a perspective view of yet another alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The invention will be better understood from the following detailed description of preferred embodiments thereof, taken in conjunction with the accompanying drawing figures, wherein:

Fig. 1 is a schematic view of a patient prepared to undergo a cardiovascular surgical procedure, the patient's heart being exposed via a retractor positioned in a thoracotomy formed in the patient's chest;

Fig. 2 is a perspective view of the heart shown in Fig. 1, wherein a portion of the heart wall is broken away for clarity;

Fig. 2A is an enlarged view of a portion of Fig. 2;

Figs. 3A-3B are perspective views showing a tissue engaging device constructed according to one embodiment of the invention, the device being shown in collapsed and expanded orientations, respectively;

Figs. 4A-4B are elevation views, in section, illustrating one preferred construction of a tissue engaging device according to the embodiment of Figs. 3A-3B, wherein the device is shown being used to engage the heart wall shown in Figs. 2-2A;

Figs. 5A-5B are elevation views, in section, illustrating another preferred construction of a tissue engaging device according to the embodiment of Figs. 3A-3B, wherein the device is shown being used to engage the heart wall shown in Figs. 2-2A;

Figs. 6A-6C are elevation views, in section, sequentially illustrating a vessel support device constructed according to another embodiment of the invention being used to support the wall of a vascular structure;

Fig. 7 is a perspective view of a vessel support device constructed according to an alternative embodiment of the invention, the device being shown positioned in the interior of a vascular structure;

Figs. 8A-8B are elevation views, in section, sequentially illustrating the device shown in Fig. 7 being used to support a coronary artery of the heart shown in Figs. 2-2A;

Fig. 9 is a perspective view of a vessel support device constructed according to another alternative embodiment of the invention, the device being shown positioned in the interior of a vascular structure;

Figs. 10A-10B are elevation views, in section, sequentially illustrating the device shown in Fig. 9 being used to support a coronary artery of the heart shown in Figs. 2-2A;

Figs. 11A-11B are plan views of a tissue engaging device constructed according to another embodiment of the invention, wherein the device is shown engaging the wall of the heart shown in Figs. 2-2A in non-retracting and retracting orientations, respectively;

Figs. 12A-12B are elevation views, in section, taken along lines A-A in Figs. 11A-11B;

Fig. 13 is an elevation view, in section, of an alternative tissue engaging device constructed according to the embodiment shown in Figs. 12A-12B;

Figs. 14A-14B are elevation views of a tapered balloon forming part of another embodiment of the invention, wherein the balloon is shown in its collapsed and expanded orientations, respectively;

Figs. 15A-15B are elevation views of an expandable conduit mounted on the tapered balloon shown in Figs. 14A-14B, the conduit being shown in its collapsed and expanded orientations, respectively;

Fig. 16 is an elevation view, in section, of a portion of a heart wall and coronary vessel in which the conduit shown in Fig. 15A-15B has been positioned;

Figs. 17A-17B are elevation views showing a conduit constructed according to still another embodiment of the invention, wherein the conduit has a cross-sectional size that varies over its length;

Fig. 18 is a perspective view of another embodiment of the invention providing a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel;

Figs. 19A-19C are schematic representations of a preferred application for the conduit shown in Fig. 18;

Fig. 20 is a perspective view of an alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel;

Fig. 21 is a perspective view of another alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel; and

Fig. 22 is a perspective view of yet another alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel.

WHAT IS CLAIMED IS:

1. A device for engaging tissue of a coronary vessel or heart wall during a cardiovascular procedure, the device comprising:

a first member;

a second member coupled to the first member so as to permit relative movement of the first and second members; and

a tissue engaging mechanism coupled to the first and second members so as to be movable between a first position and a second, actuated position, the tissue engaging mechanism including at least one tissue engaging member configured to engage body tissue when the tissue engaging mechanism is in the second actuated position;

wherein relative movement of the first and second members moves the tissue engaging mechanism between the collapsed and expanded orientations to selectively place the tissue engaging member in engagement with body tissue.

2. The device of claim 1, wherein the first and second members are first and second coaxial shafts with the tissue engaging mechanism extending therebetween, and relative axial movement of the first and second shafts moves the tissue engaging mechanism between a collapsed orientation and an expanded orientation.

3. The device of claim 2, wherein each of the first and second shafts has a proximal end and a distal end, and the tissue engaging mechanism is disposed adjacent the distal ends of the shafts.

4. The device of claim 3, wherein at least one of the first and second shafts has a portion configured to be passed through and dilate an opening in tissue, wherein the tissue engaging mechanism may be positioned adjacent tissue and then expanded to engage the tissue.

5. The device of claim 1, further comprising an actuator coupled to the first and second members for imparting relative movement thereto in order to move the tissue engaging mechanism between the collapsed and expanded orientations.

6. The device of claim 5, wherein the actuator comprises a handle coupled to one of the first and second members for moving the one member relative to the other member.

7. The device of claim 1, wherein the tissue engaging mechanism includes a non-inflatable structure that is moved between the collapsed and expanded orientations.

8. The device of claim 1, wherein the tissue engaging mechanism includes a plurality of tissue engaging members each of which has opposite ends coupled, respectively, to the first and second members, wherein relative movement of the first and second members imparts relative movement to the ends of the tissue engaging members to move the tissue engaging mechanism between the collapsed and expanded orientations.

9. The device of claim 1, wherein the tissue engaging mechanism includes a balloon that is inflated by pressurized fluid to engage the tissue.

10. The device of claim 1, wherein the tissue engaging mechanism includes an expandable mesh that is moved between the collapsed and expanded orientations in response to relative movement of the first and second members.

11. The device of claim 1, wherein first and second tissue engaging mechanisms are coupled to the first and second members so that each mechanism is movable between a collapsed orientation and an expanded orientation, the first and second tissue engaging mechanisms being spaced from each other to permit body tissue to be captured therebetween with the first and second tissue engaging mechanisms engaging opposite surfaces of the body tissue.

12. A method for supporting heart tissue during a medical procedure, the method comprising steps of:

providing a tissue support device having a tissue engaging mechanism configured to assume an expanded, tissue supporting orientation;

positioning the tissue support device through the wall of a patient's heart and locating the tissue engaging mechanism adjacent heart tissue; and

placing the tissue engaging mechanism in the expanded, tissue supporting orientation in engagement with the heart tissue.

13. The method of claim 12, further comprising positioning a conduit in the wall of the heart to place a coronary vessel in communication with a heart chamber.

14. A device for supporting a wall of a vascular structure, the device comprising:

a support structure adapted to be removably positioned in the lumen of a vascular structure, the support structure comprising a plurality of support elements coupled together so as to be movable relative to each other, wherein moving the support elements relative to each other moves the support structure from a collapsed orientation to an expanded orientation in order to support a wall of a vascular structure; and

wherein the support elements are sized and configured for positioning in the interior of the vascular structure such that when the support structure is in the expanded orientation the support elements engage the wall of the vascular structure to prevent the wall from collapsing.

15. The device of claim 14, wherein the support elements comprise a plurality of flexible struts each of which has a free end, wherein the free ends of the struts are moved apart to place the support structure in the expanded orientation.

16. The device of claim 15, further comprising a sheath coupled to the flexible struts so that movement of the sheath relative to the struts moves the free ends of the struts apart to place the support structure in the expanded orientation.

17. The device of claim 14, wherein the support elements comprise a plurality of flexible struts each of which has first and second ends and a central portion between the ends, wherein the first ends of the struts are fixed to each other and the second ends of the struts are fixed to each other such that the central portions of the struts move away from each other as the support structure moves to the expanded orientation.

18. The device of claim 16, further comprising a sheath slidable over the flexible struts, wherein the sheath is placed over at least a portion of the struts to move the support structure to the collapsed orientation and is removed from the said portion of the struts to move the support structure in the expanded orientation.

19. A device for supporting a vascular structure, the device comprising:

an introducer having a hollow interior;

an elongated support member configured to be generally coiled when in an unbiased orientation and generally straight when in a biased orientation;

wherein the interior of the introducer is sized and configured to receive the elongated support member and hold the support member in the generally straight, biased orientation; and

wherein the elongated support member is moved from the straight, biased orientation within the interior of the introducer to the coiled, unbiased orientation upon entering the interior of the vascular structure to support the vascular structure.

20. The device of claim 19, wherein the elongated support member is a superelastic wire that is generally straight when in the biased orientation and generally helical when in the unbiased orientation.

21. The device of claim 20, wherein an end of the elongated support member is sharpened for forming an opening in the wall of the vascular structure to pass the support member into the interior of the vascular structure.

22. The device of claim 19, wherein the elongated support member is adapted to be removed from the vascular structure via the opening through which the support member is passed into the vascular structure.

23. A method for internally supporting a wall of a vascular structure, the method comprising steps of:

(a) positioning a support within an interior of a vascular structure such that the support contacts and supports a wall of the vascular structure; and

(b) introducing a medical device into the interior of the vascular structure by passing the device through the wall of the vascular structure and through the support.

24. The method of claim 23, wherein the support is an elongated member configured in a generally straight orientation prior to being positioned in the interior of the vascular structure and assumes a generally coiled orientation once positioned in the interior of the vascular structure, the medical device being introduced between coils of the support into the vascular structure.

25. The method of claim 23, wherein the support is movable between collapsed and expanded orientations, and step (a) is carried out by introducing the support

into the vascular structure in said collapsed orientation and then moving the support to said expanded orientation.

26. The method of claim 23, wherein the support comprises a sleeve having at least one opening formed therein through which the medical device is introduced.

27. The method of claim 23, wherein the vascular structure is a coronary artery and the medical device is a conduit delivery device that is passed through the coronary artery to position a conduit in the wall of the heart to communicate the coronary artery with a heart chamber.

28. The method of claim 23, further comprising the step of removing the medical device and the support from the vascular structure.

29. A method for supporting a wall of a vascular structure at an area adjacent an incision in the wall of the vascular structure, the method comprising steps of:

inserting a support through the incision in the wall of the vascular structure while the support is in a low profile orientation;

positioning at least a portion of the support within the interior of the vascular structure; and

moving the support from the low profile orientation into an expanded orientation so as to contact and support the wall of the vascular structure.

30. The method of claim 29, further comprising introducing a medical device into the interior of the vascular structure by passing the device through the support.

31. The method of claim 30, wherein the vascular structure is a coronary artery and the medical device is a conduit delivery device that is passed through the coronary artery to position a conduit in the wall of the heart to communicate the coronary artery with a heart chamber.

32. A device for stabilizing an area of a patient's heart adjacent a coronary vessel, the device comprising:

a base configured to be positioned adjacent a coronary vessel of a patient's heart, the base having at least one opening for accessing the coronary vessel;

at least one tissue engaging element coupled to the base so as to be movable with respect to the base, the tissue engaging element having a portion configured to securely engage the wall of a patient's heart in order to stabilize the wall of the heart upon moving the tissue engaging element with respect to the base; and

an actuator for imparting relative movement to the base and the tissue engaging element in order to stabilize the heart while accessing the coronary vessel through the opening in the base.

33. The device of claim 32, wherein the base has a single opening for accessing the coronary vessel and a plurality of tissue engaging elements are coupled to the base.

34. The device of claim 33, wherein the tissue engaging elements comprise legs each of which has one end pivotally attached to the base and another end provided with a member configured to at least partially penetrate the wall of the heart.

35. The device of claim 34, wherein the base has a plurality of recesses each of which pivotally mounts the one end of one of the legs, each recess having a cam surface that moves the leg with respect to the base when the base is rotated.

36. The device of claim 32, wherein the tissue engaging elements include a sharpened end configured to partially penetrate the wall of the heart.

37. The device of claim 36, wherein each tissue engaging element has an end provided with an expandable member, the expandable member configured to be passed through the wall of the heart to a location adjacent a surface of the wall opposite the coronary vessel and then expanded to engage said surface of the wall.

38. A conduit for placing a coronary vessel of a patient's heart in communication with a heart chamber, the conduit comprising:

a tubular element including first and second portions having different cross-sectional sizes, the tubular element having a bore defining a blood flow path;

wherein the cross-section of the first portion of the tubular element is larger than the cross-section of the second portion of the tubular element such that the tubular element is generally funnel-shaped; and

wherein the first and second portions of the tubular element are generally aligned and the bore defines a generally straight blood flow path.

39. A conduit for communicating a chamber of a patient's heart with a coronary vessel, the conduit comprising:

an expandable stent including first and second ends and a length defined between the ends, the length of the stent including first and second portions having different cross-sectional sizes when the stent is expanded;

wherein each of the first and second portions of the stent includes strut members disposed along a first direction when the stent is unexpanded and along a second direction when the stent is expanded, the second direction being transverse to the first direction; and

wherein the strut members of the first portion are longer than the strut members of the second portion and the stent is generally funnel-shaped when expanded.

40. A device for use in a coronary vessel of a patient's heart, the device comprising:

an expandable stent including a bore defining a blood flow path and first and second portions, the first and second portions having different cross-sectional sizes when the stent is expanded;

wherein the first portion has a larger cross-sectional dimension than the second portion when the stent is expanded such that the stent is generally funnel-shaped when expanded; and

wherein the first and second portions of the stent are constructed to provide the stent with maximum radial strength when expanded.

41. The device of claim 40, wherein the stent is configured to be positioned and retained in a heart wall to place a coronary vessel in communication with a heart chamber.

42. The device of claim 40, wherein the stent has a plurality of openings along the length of the stent through which blood may flow.

43. A method for placing a generally funnel-shaped conduit in a wall of a patient's heart to communicate a heart chamber with an interior of a coronary vessel located near the exterior of the heart, the method comprising steps of:

(a) providing a conduit having a length, a first end, and a second end, wherein the conduit is generally straight and the second end has a larger cross-section than the first end such that the conduit is generally funnel-shaped;

(b) positioning the conduit in the wall of the heart to communicate the heart chamber with the interior of the coronary vessel; and

(c) orienting the conduit in the wall of the heart such that the first end is disposed adjacent the coronary vessel and the second end is disposed adjacent the heart chamber.

44. A conduit for placing a coronary vessel of a patient's heart in communication with a heart chamber, the conduit comprising:

a tubular element configured to positioned in the wall of a patient's heart, the tubular element including first and second ends and a bore defining a blood flow path; and

a vessel supporting mechanism carried by the tubular element, the vessel supporting mechanism being positioned on the conduit so as to contact and support the wall of a coronary vessel when the conduit is positioned in the heart wall.

45. The conduit of claim 44, wherein the tubular element is a rigid, solid walled structure.

46. The conduit of claim 44, wherein the tubular element is an expandable stent including a plurality of struts, and the vessel supporting mechanism comprises some of the struts.

FIG. 1

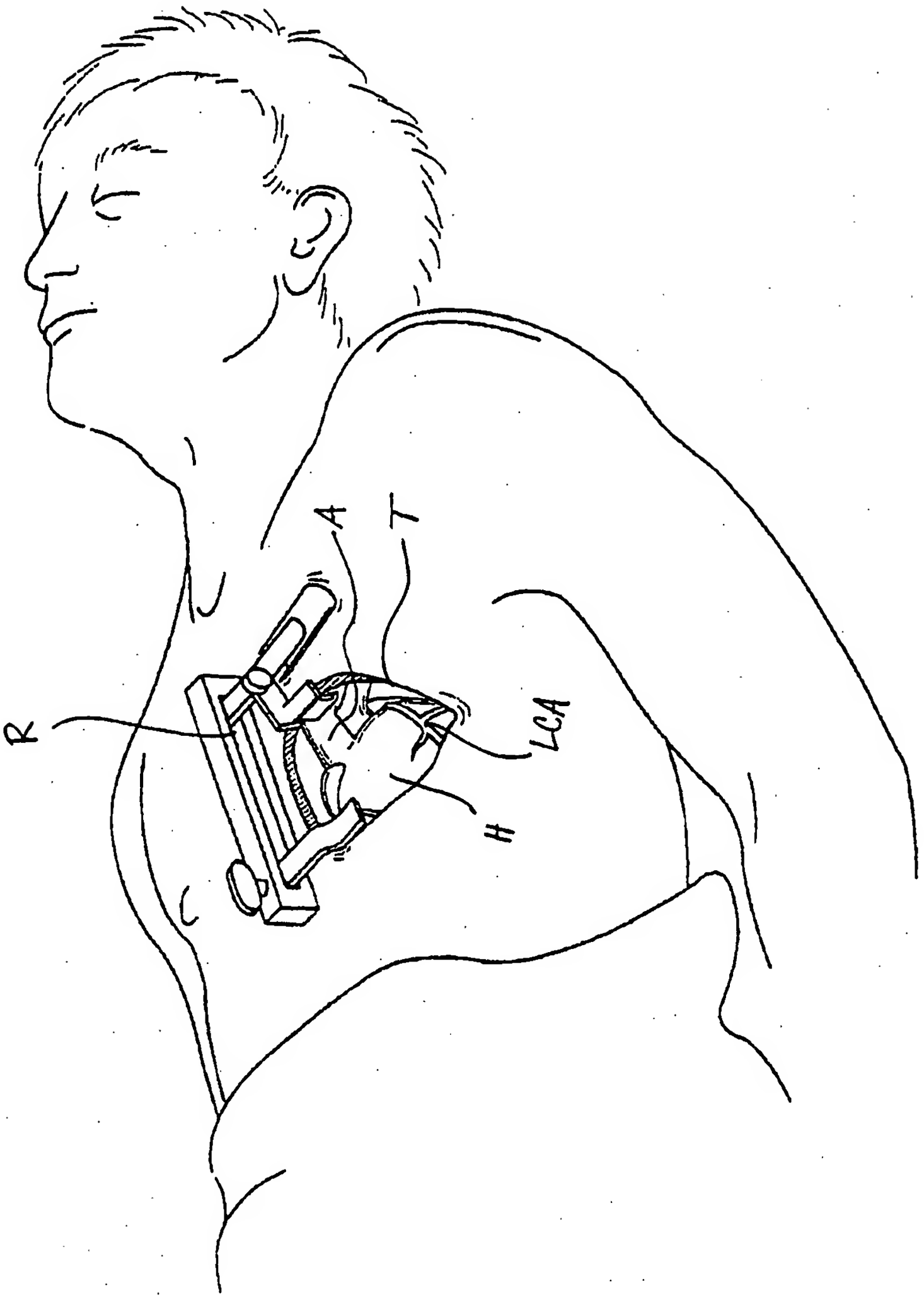


FIG. 2

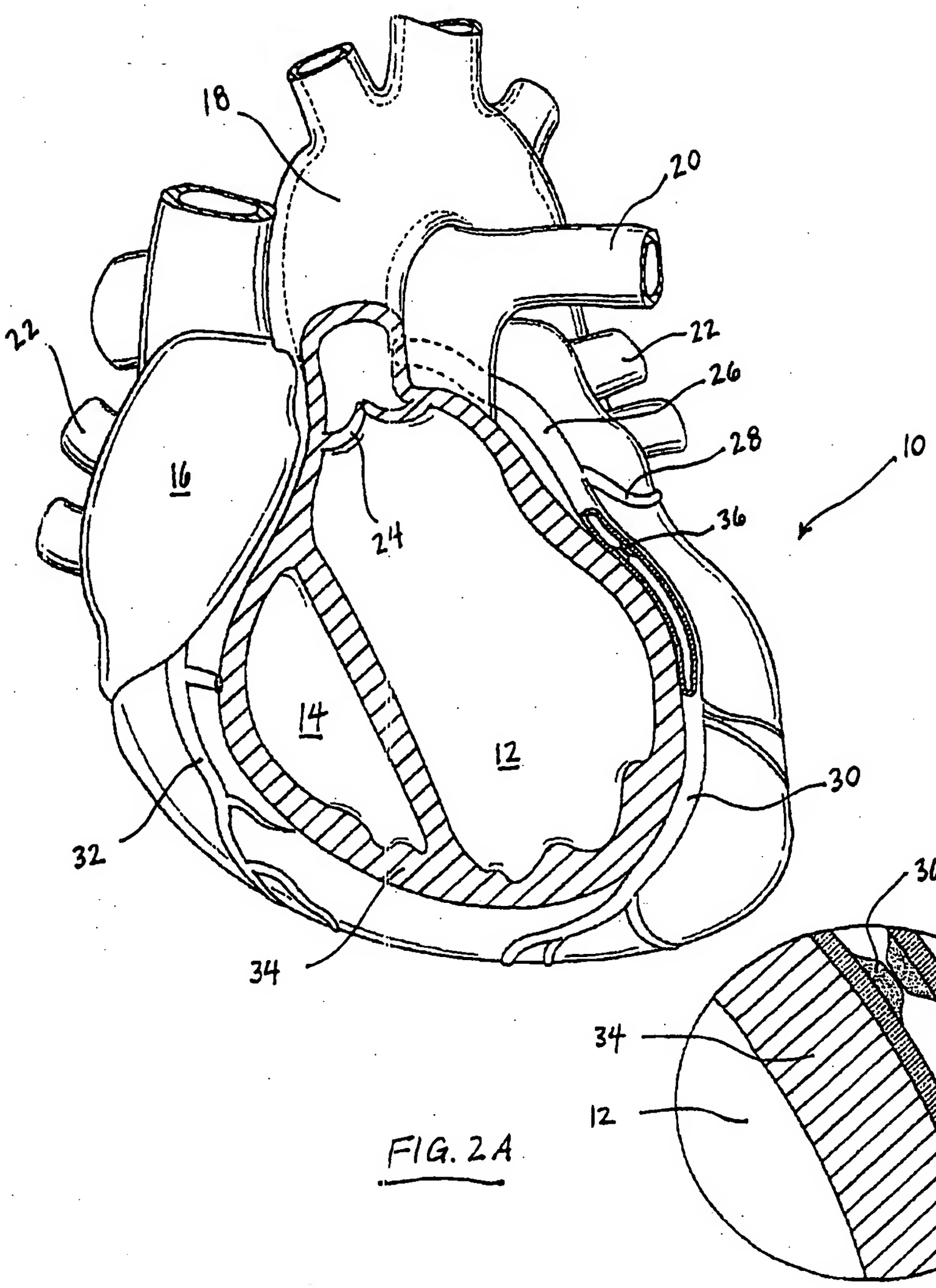


FIG. 2A

FIG. 3A

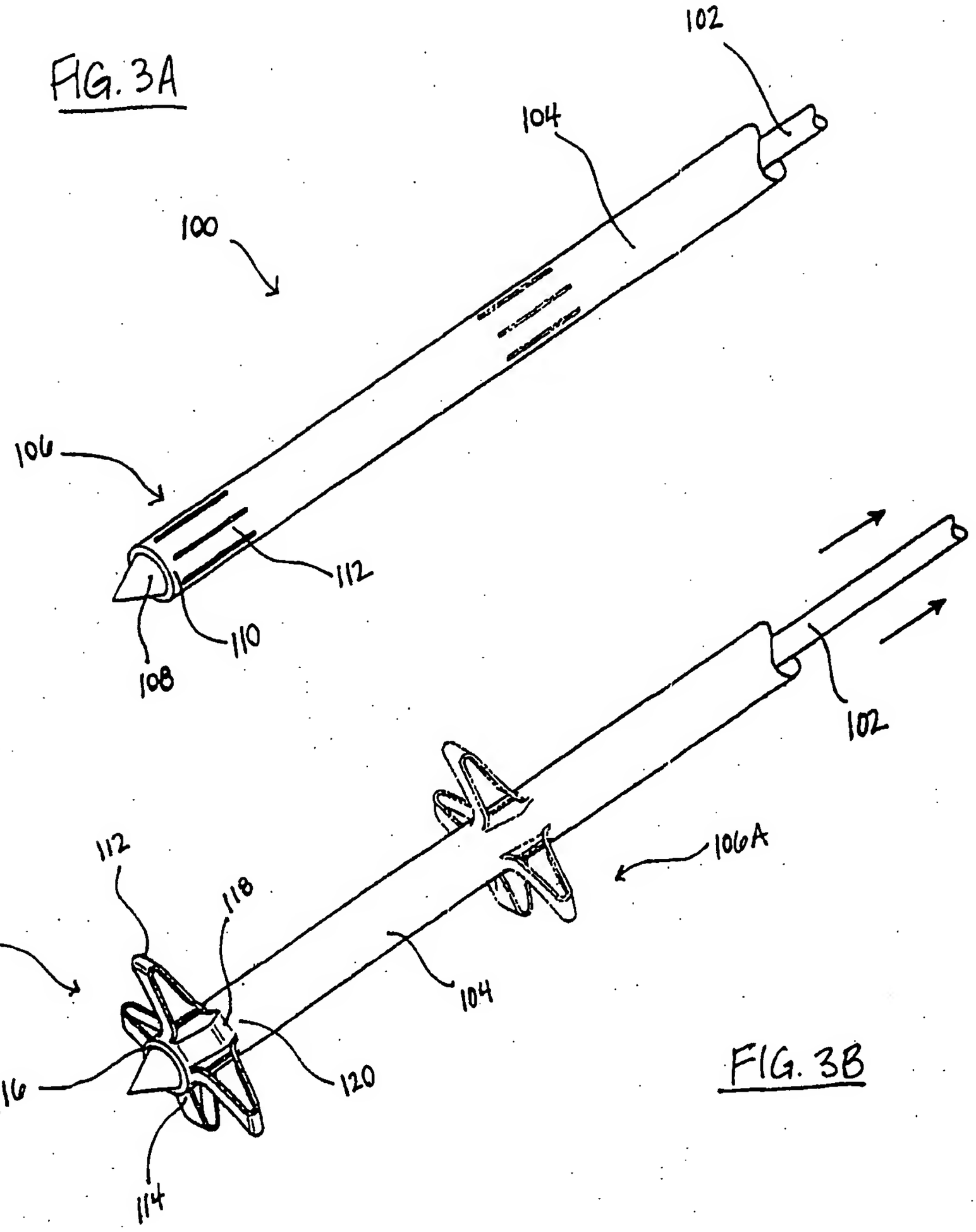


FIG. 3B

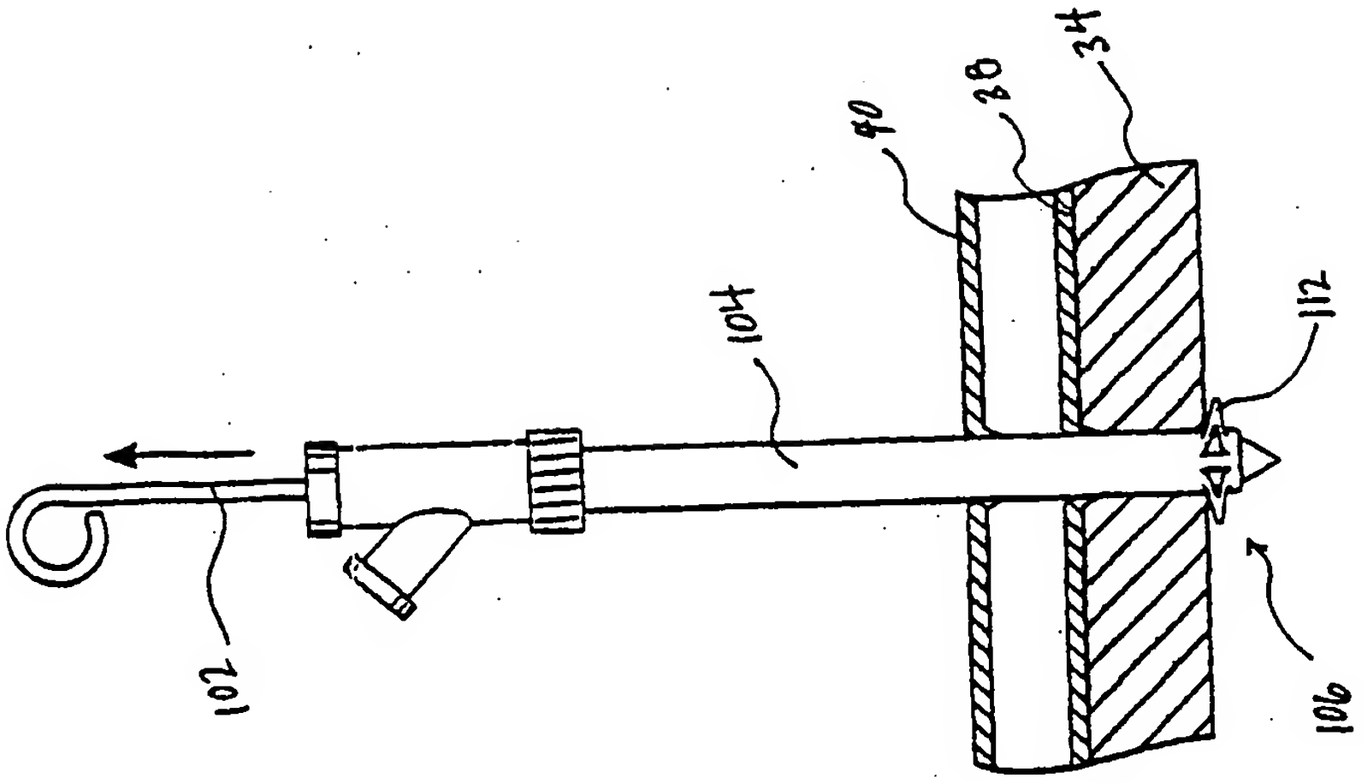


FIG. 4B

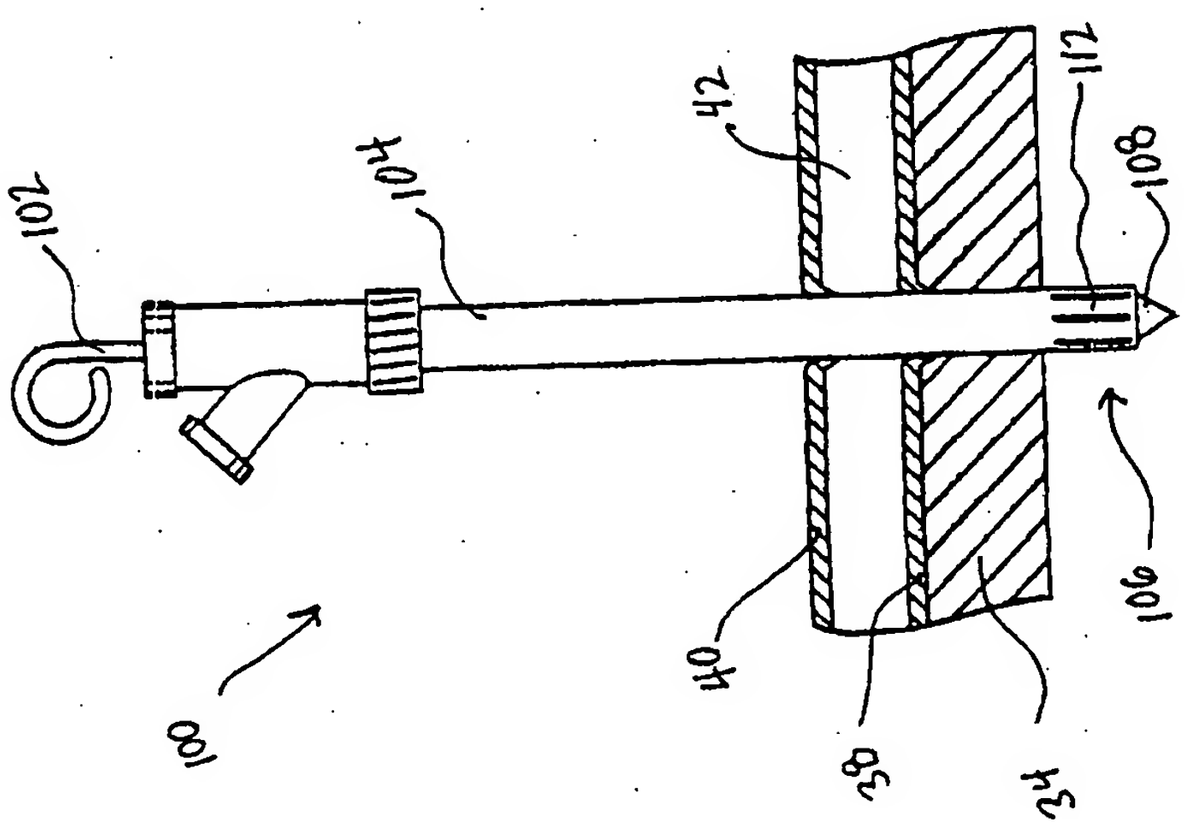


FIG. 4A

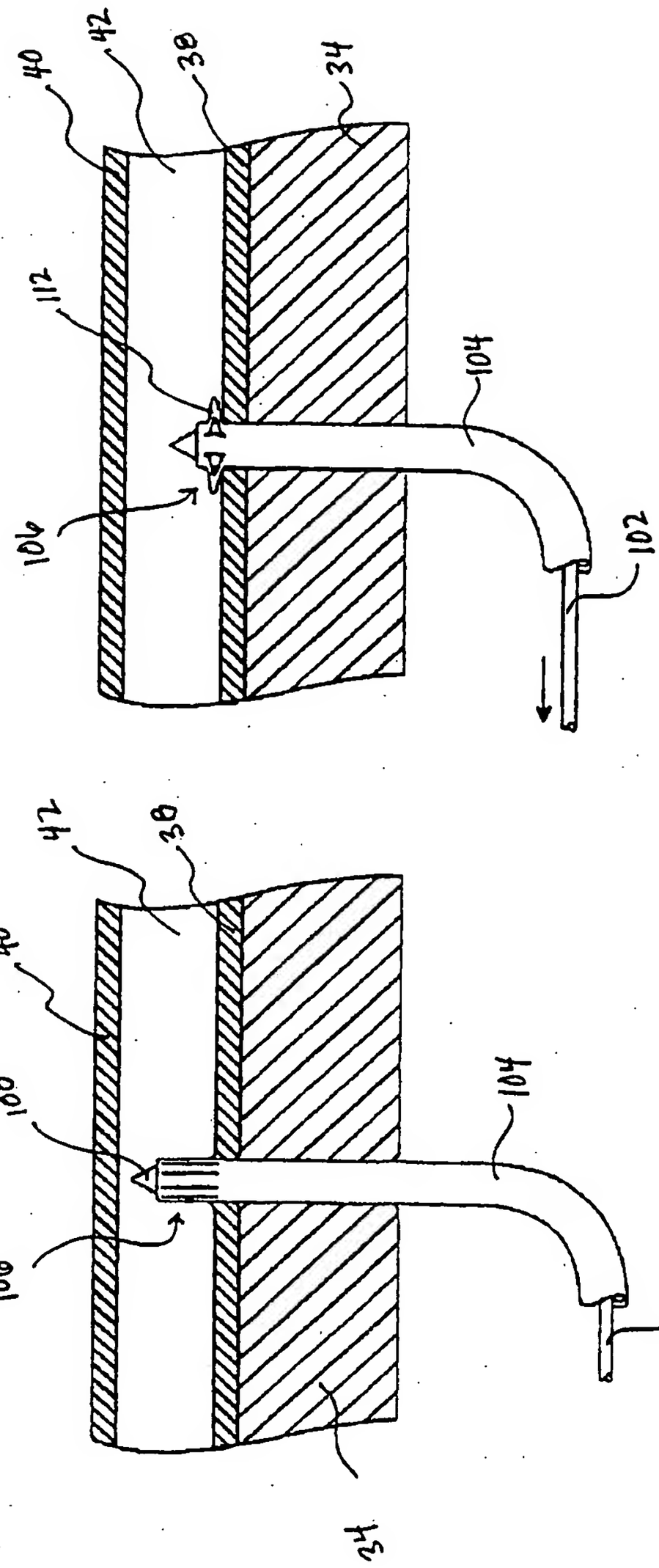


FIG. 5B

FIG. 5A

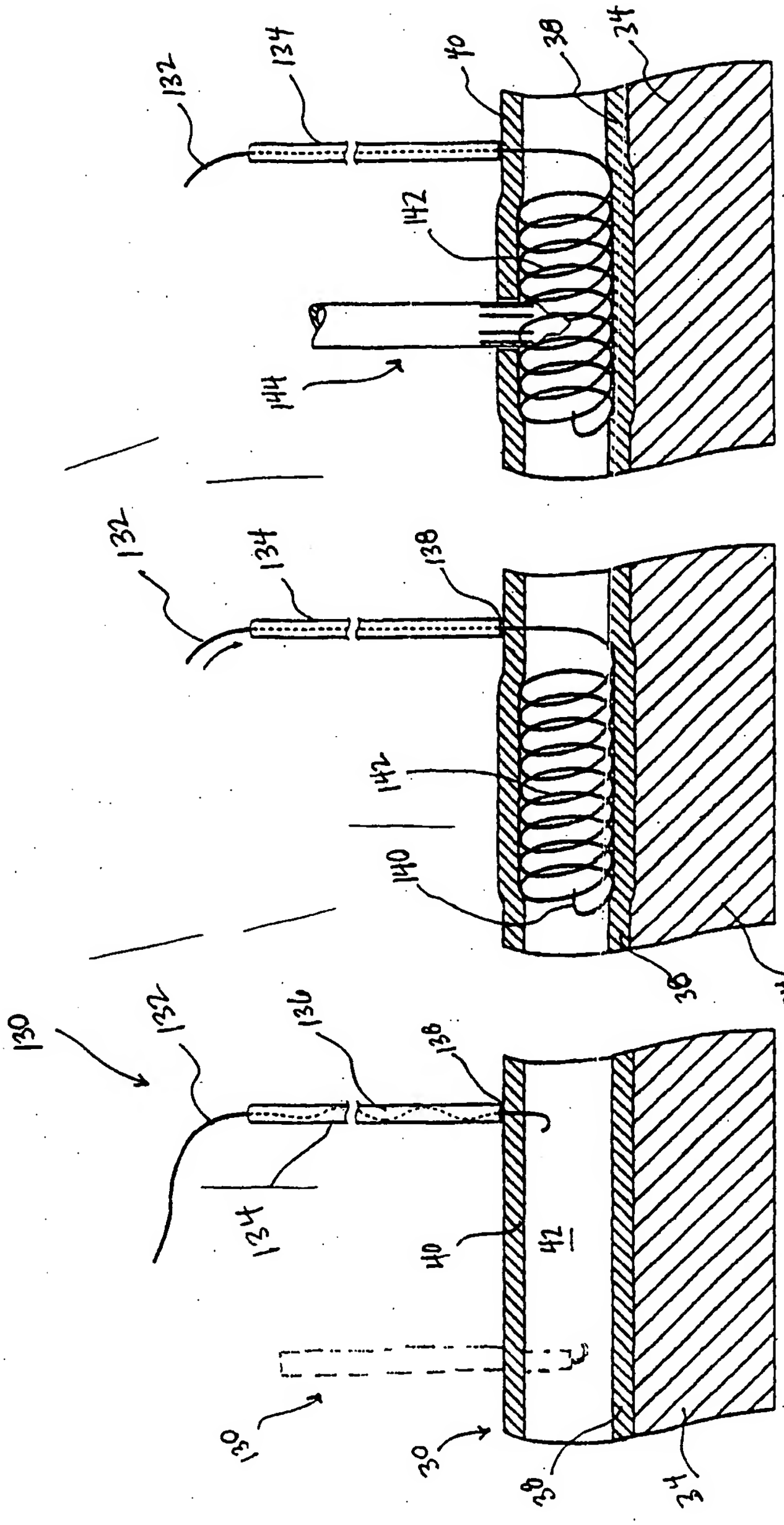


FIG. 6C

FIG. 6B

FIG. 6A

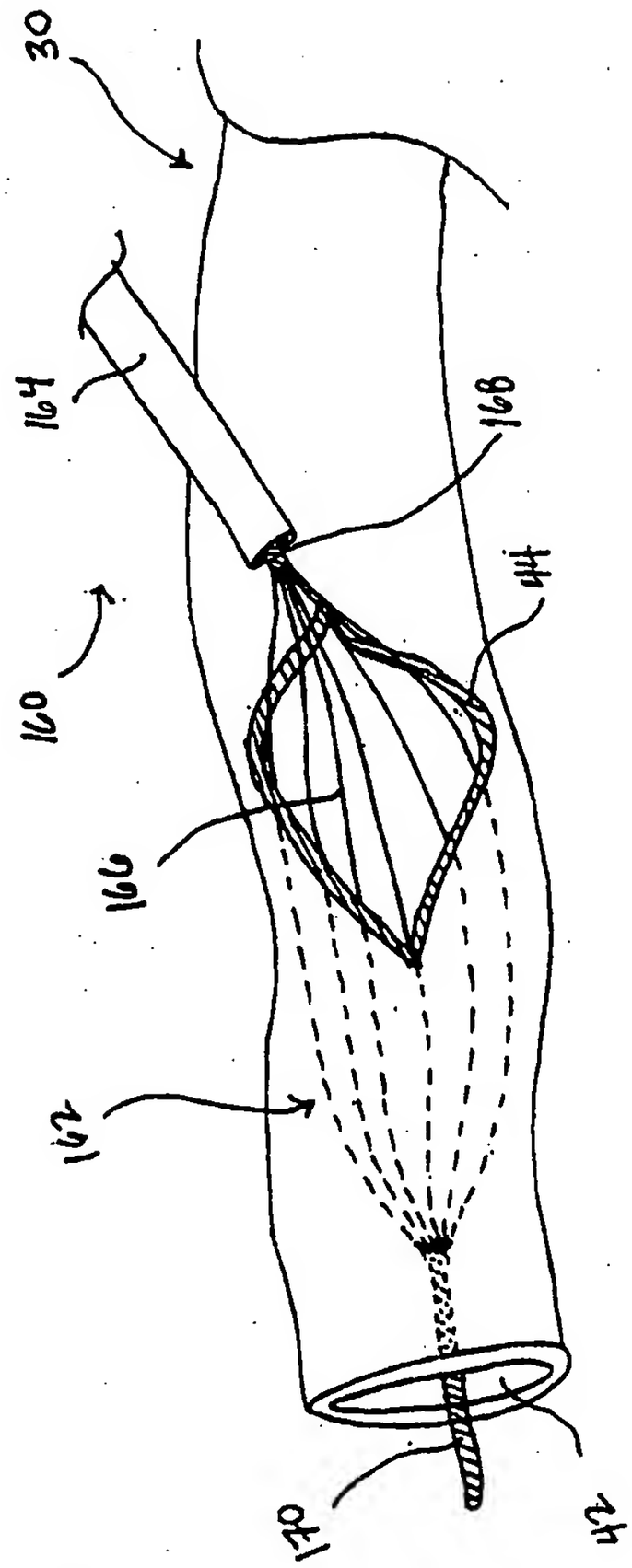


FIG. 7

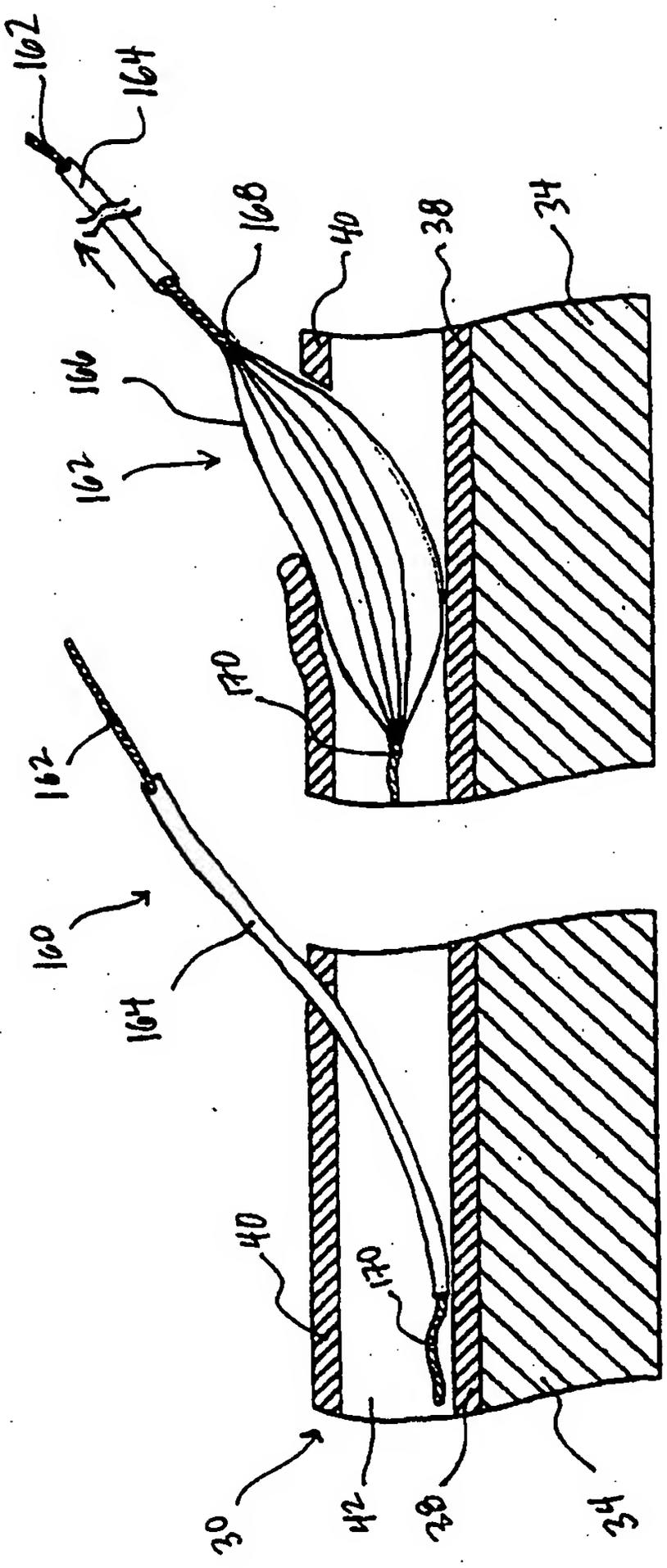


FIG. 8A

FIG. 8B

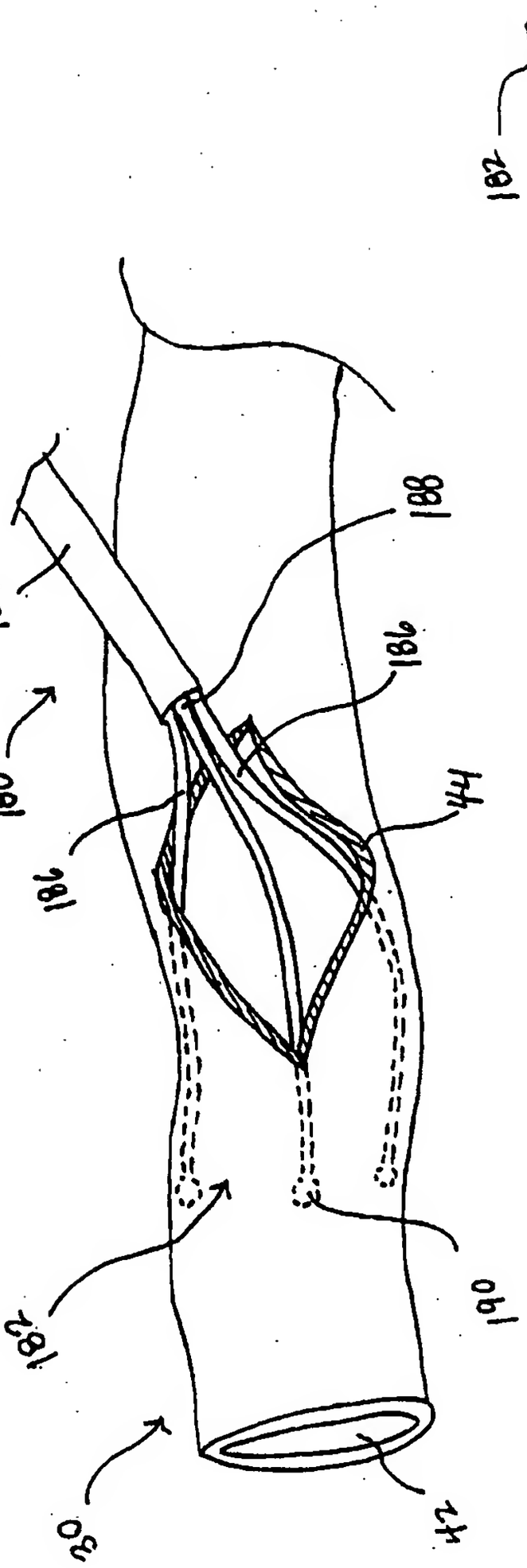


FIG. 9

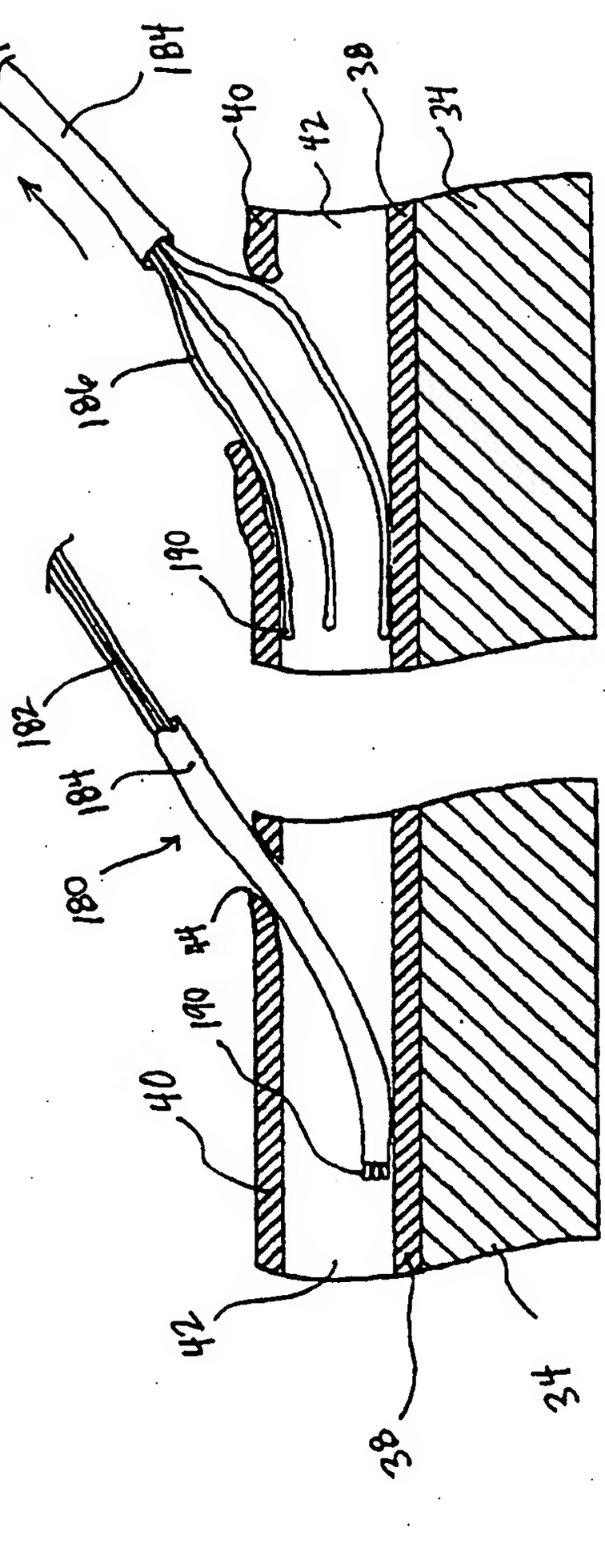


FIG. 10B

FIG. 10A

FIG. 11A

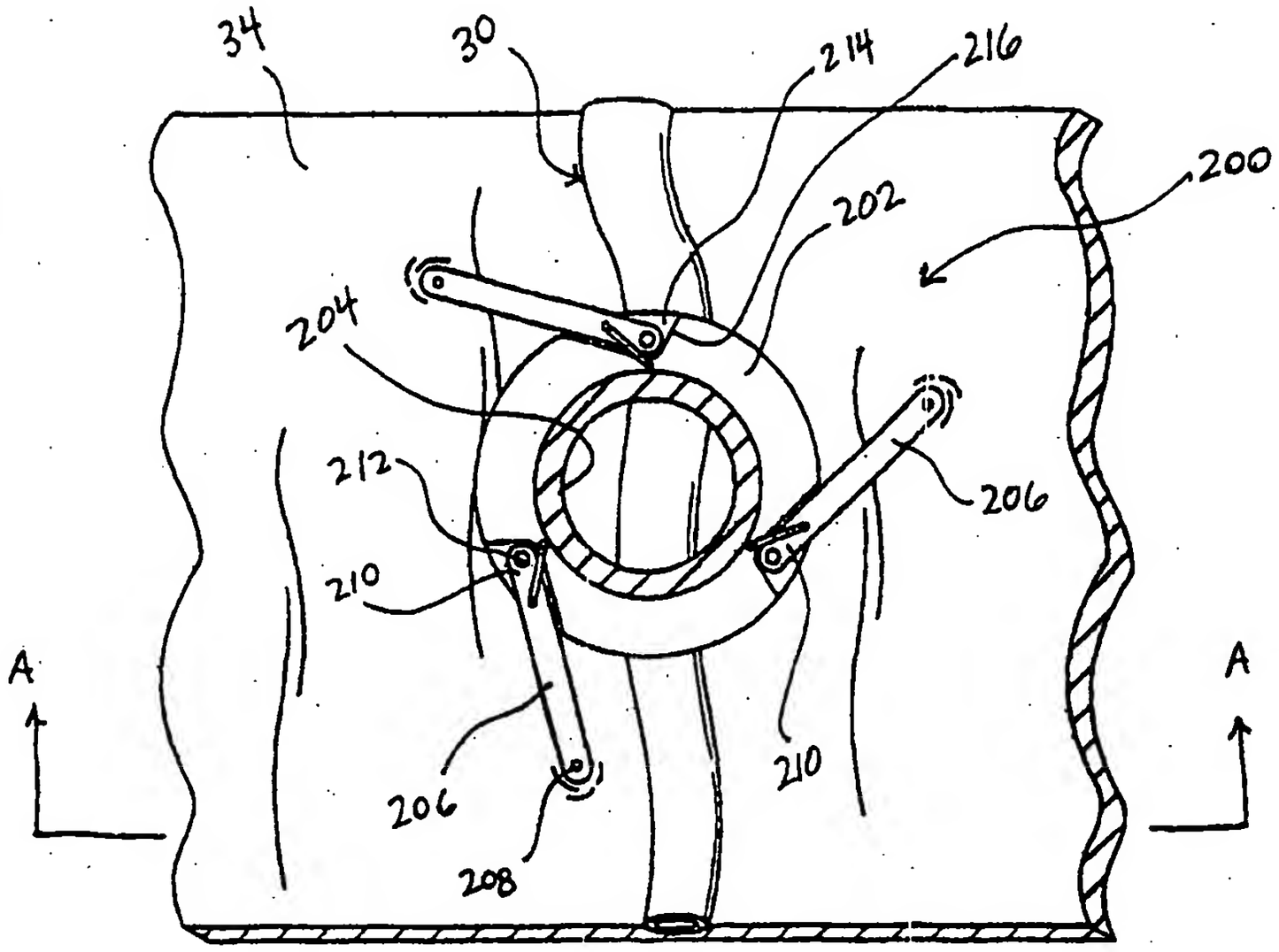


FIG. 11B

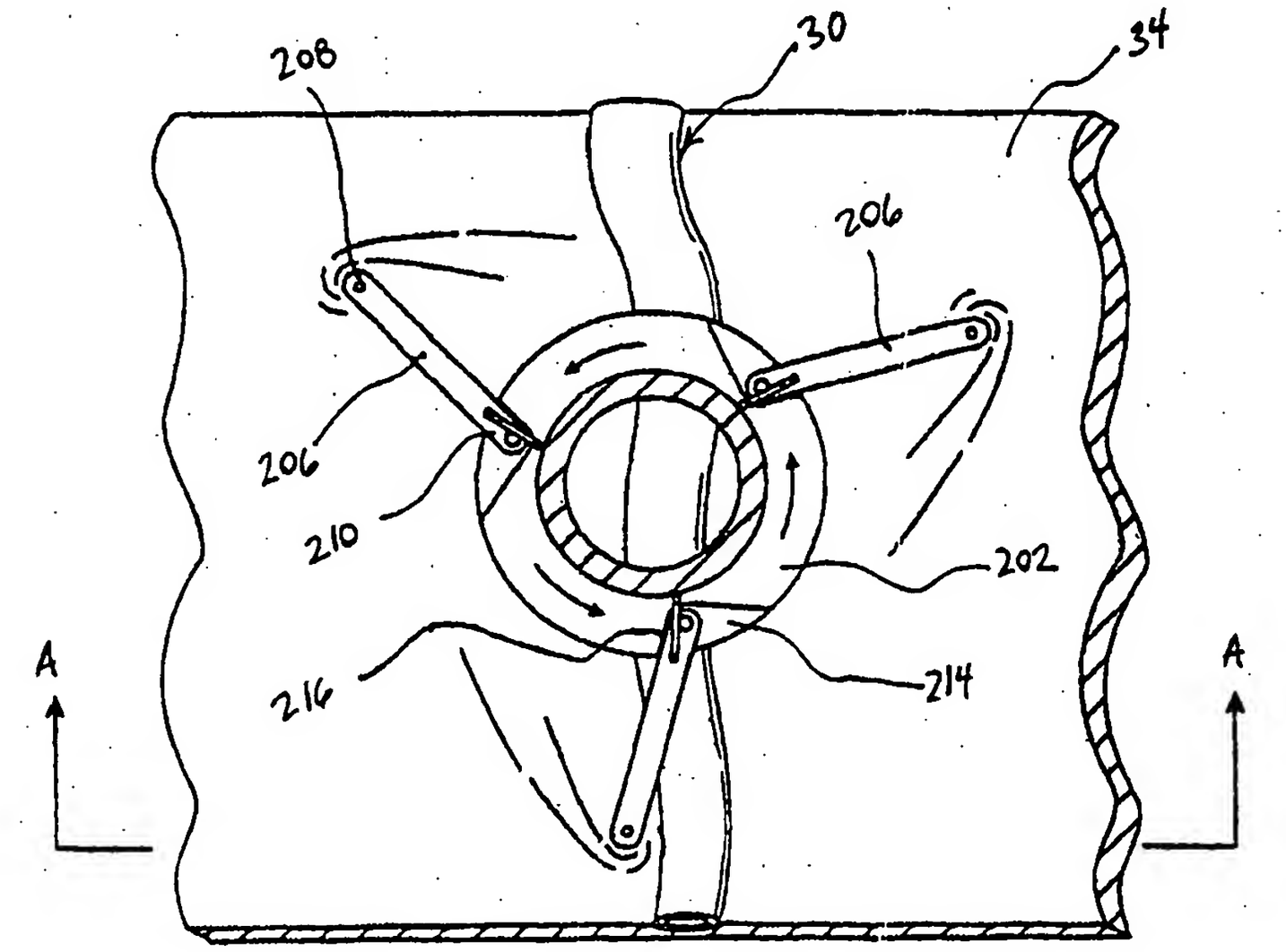


FIG. 12A

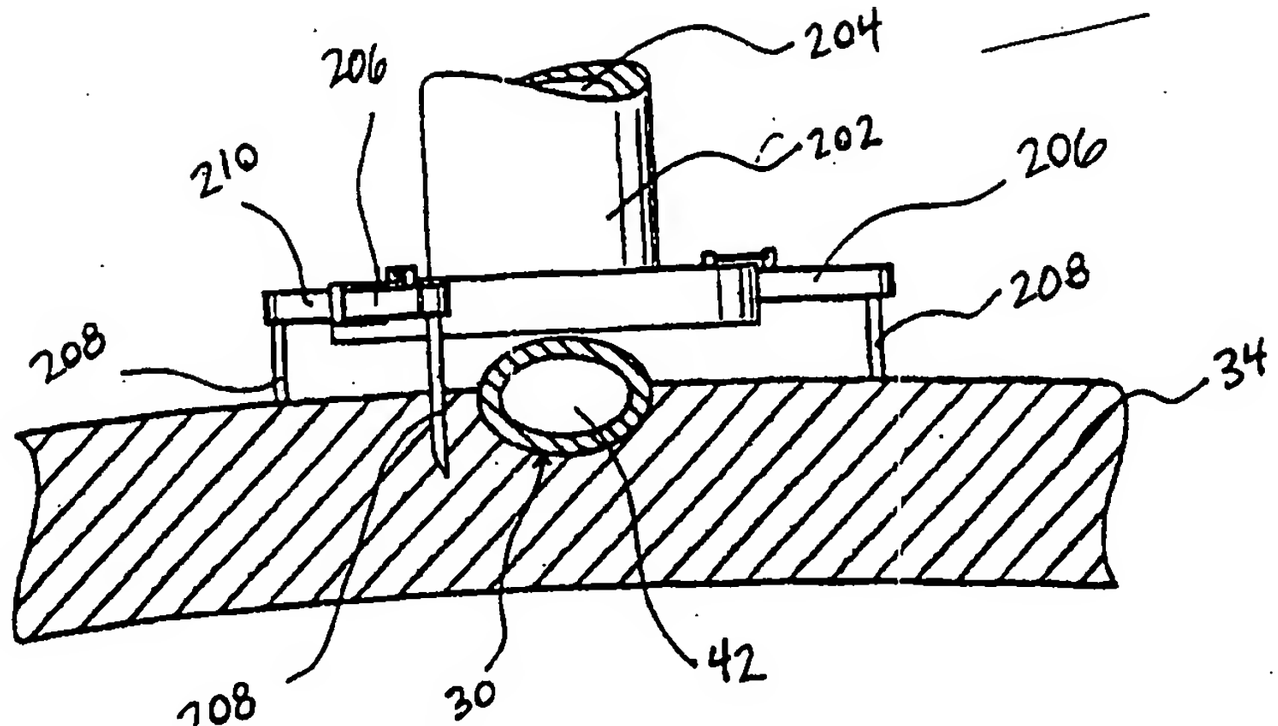


FIG. 12B

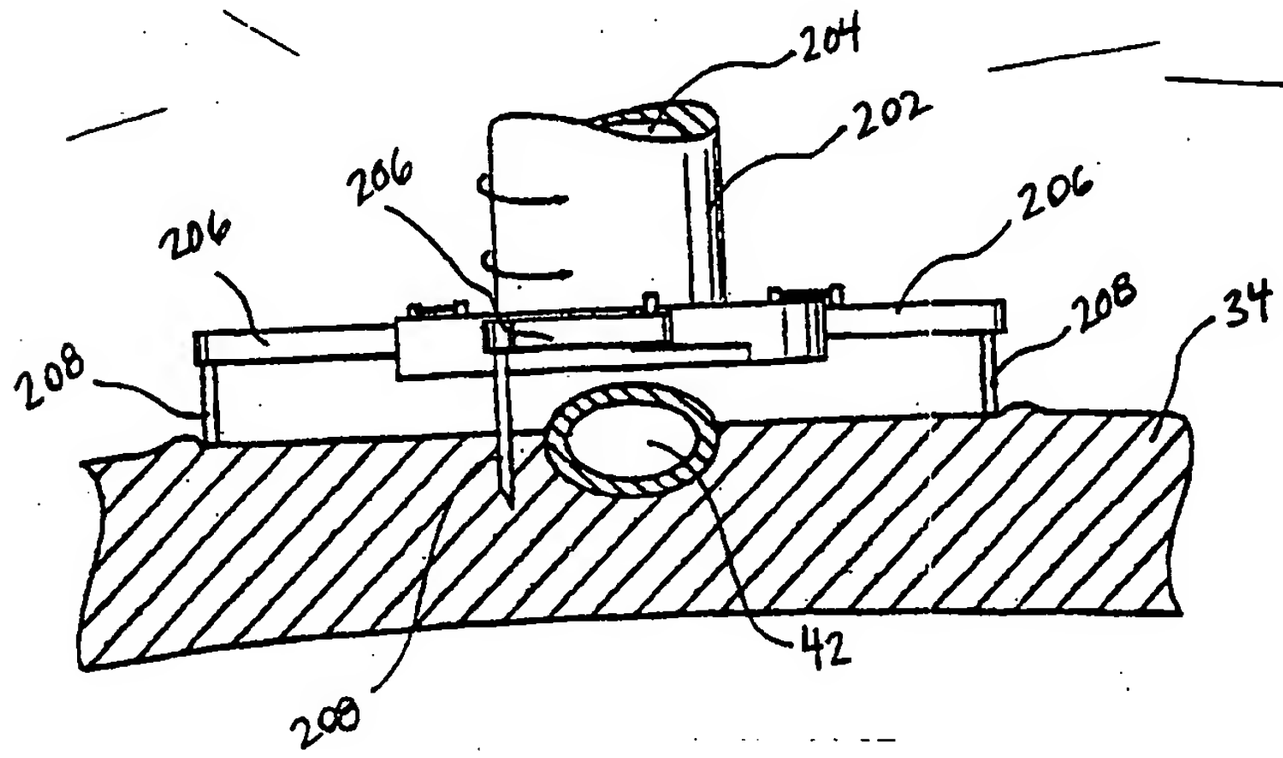


FIG. 13

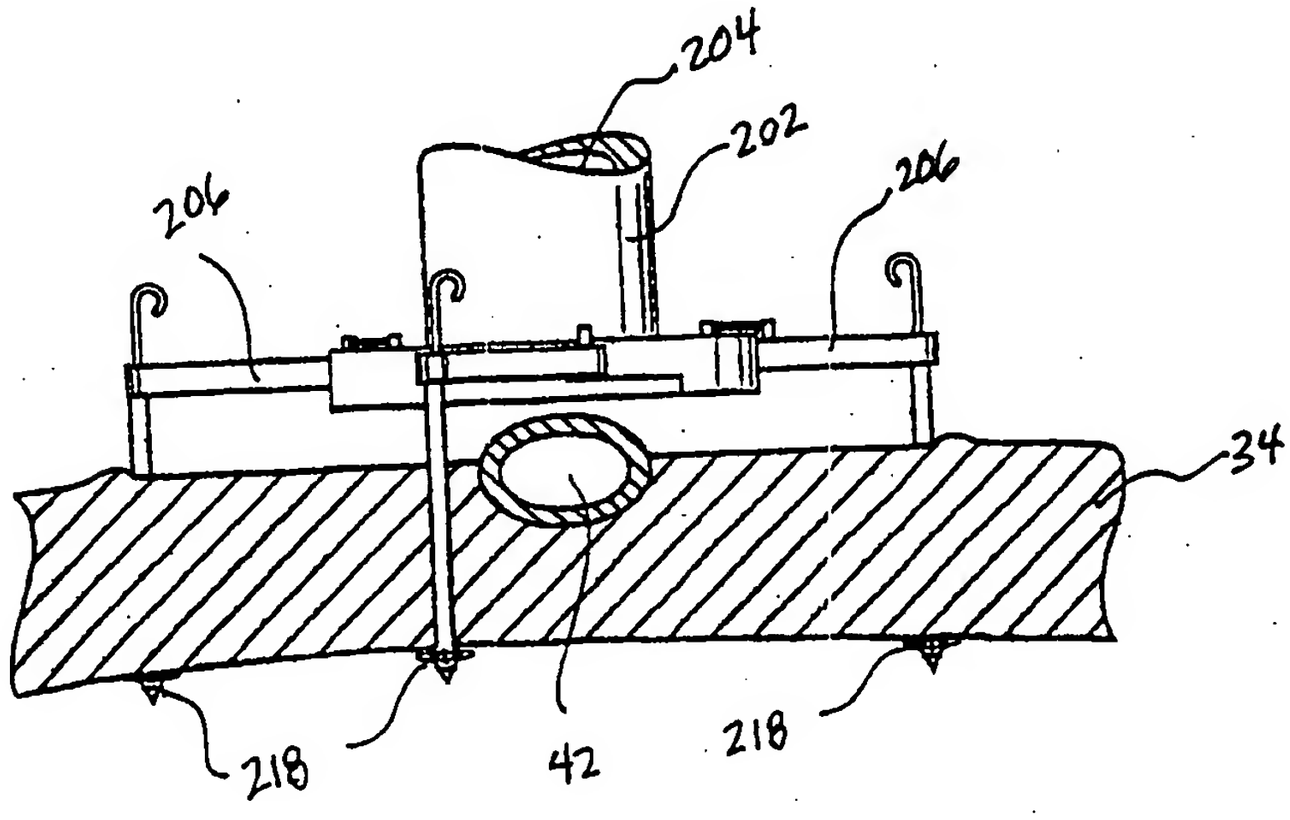


FIG. 14A

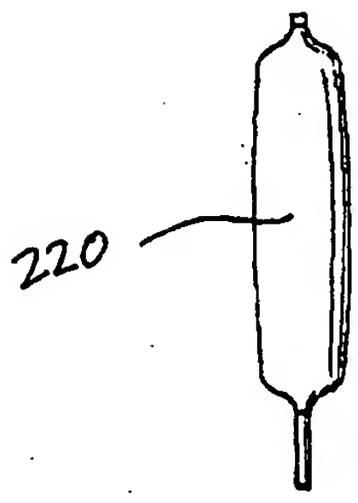


FIG. 14B

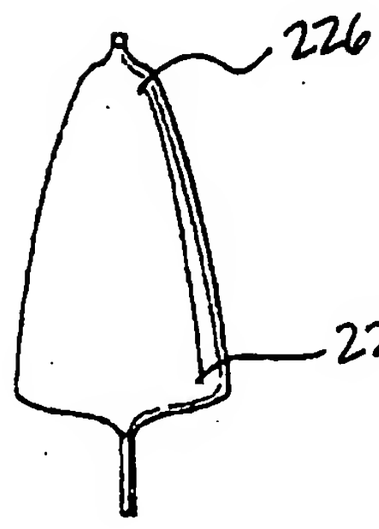


FIG. 15A

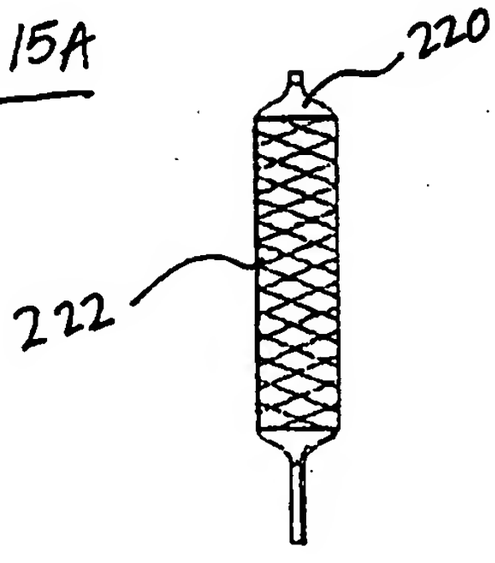


FIG. 15B

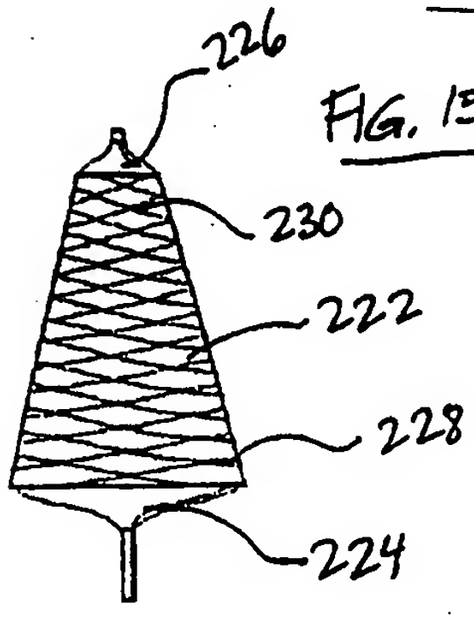
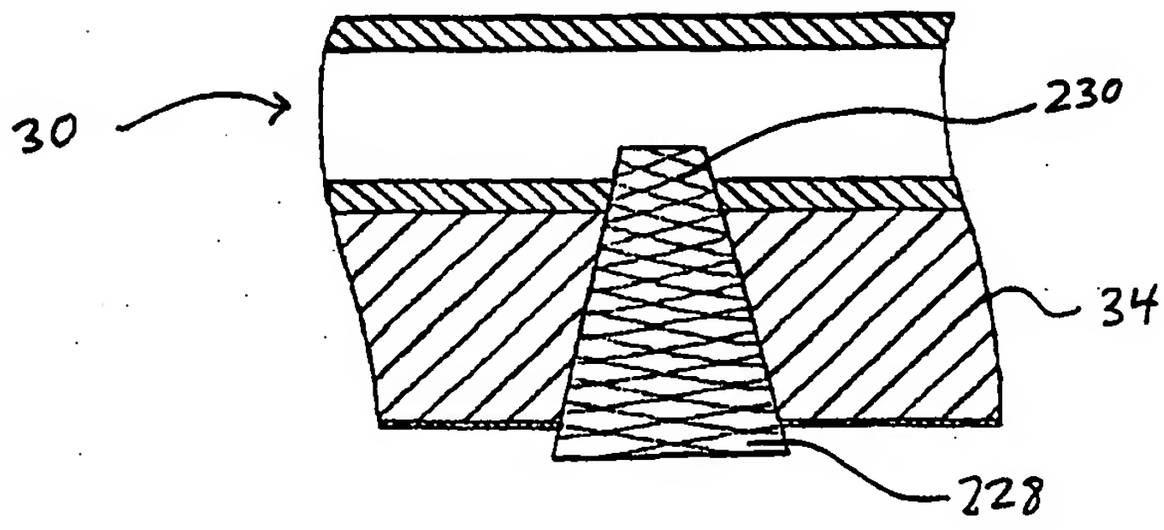


FIG. 16



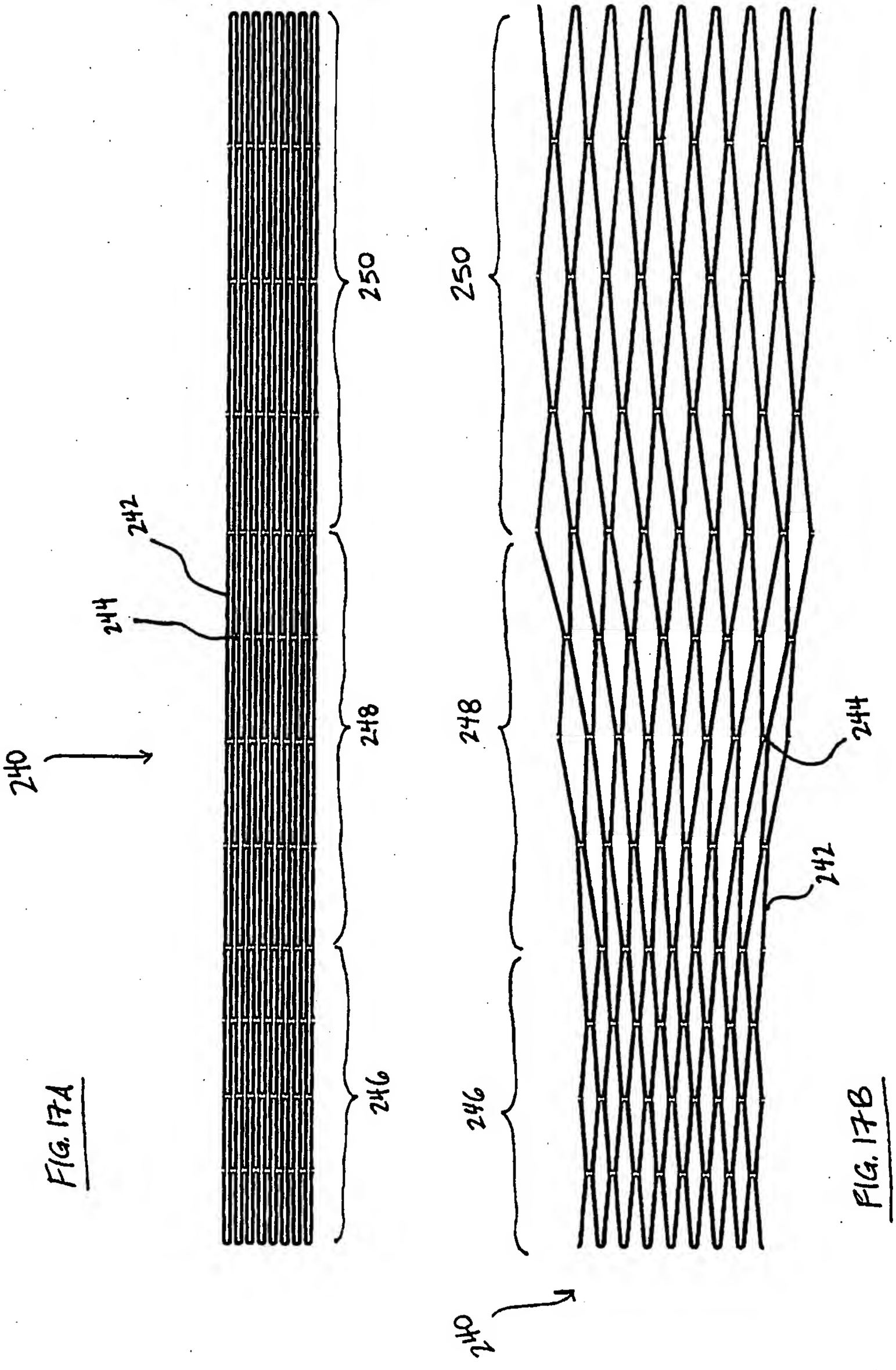


FIG. 17A FIG. 17B

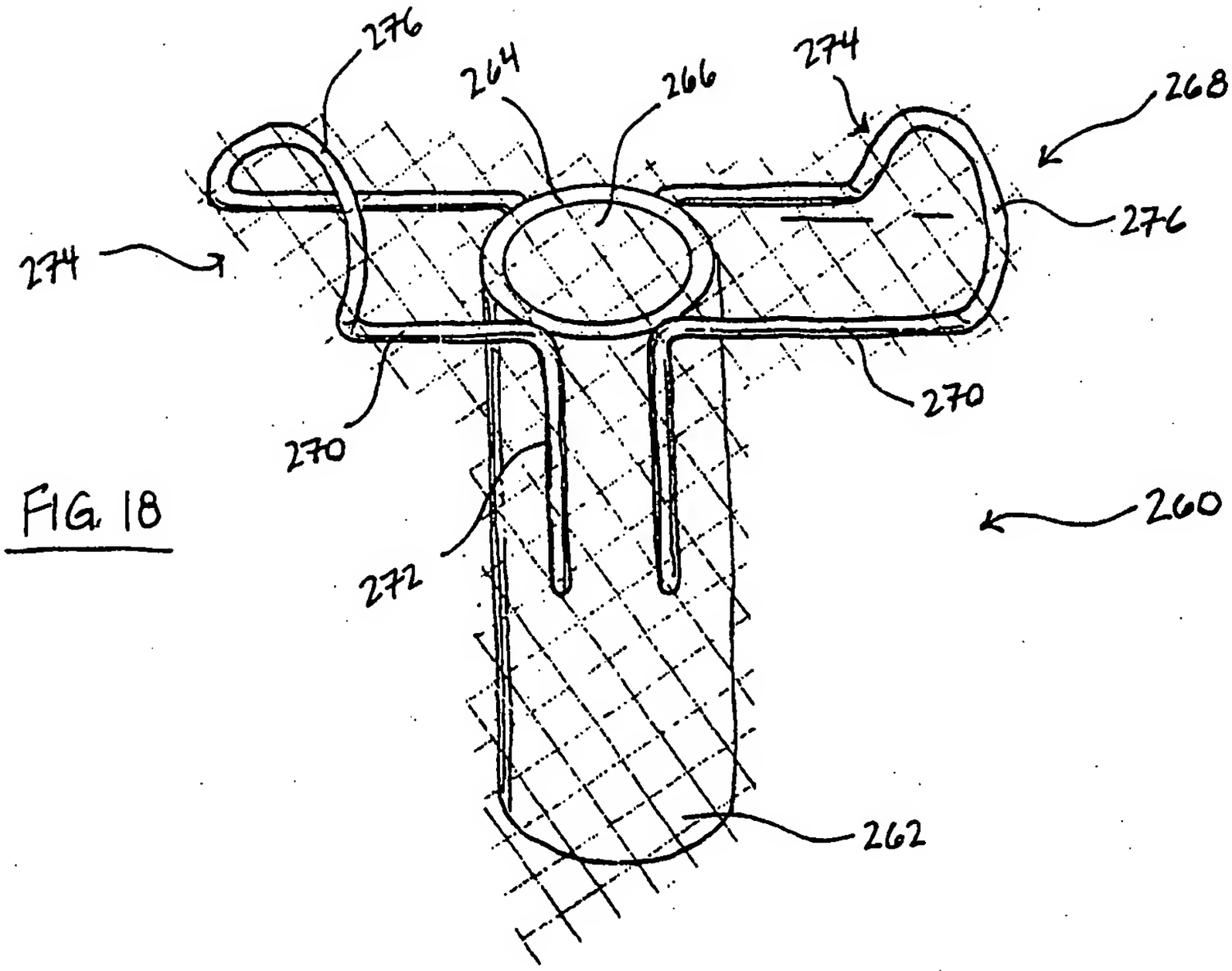


FIG. 18

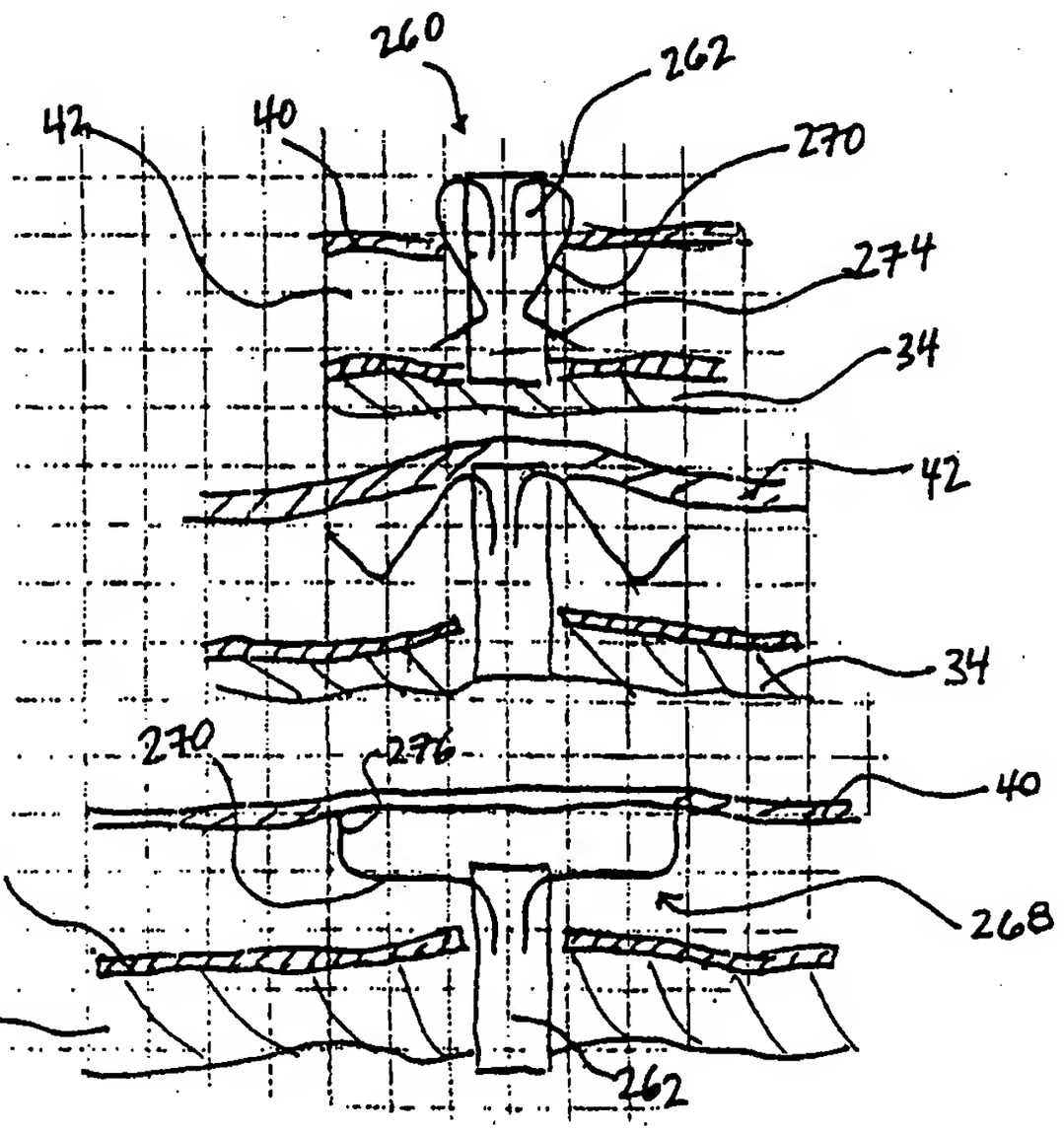


FIG. 19A

FIG. 19B

FIG. 19C

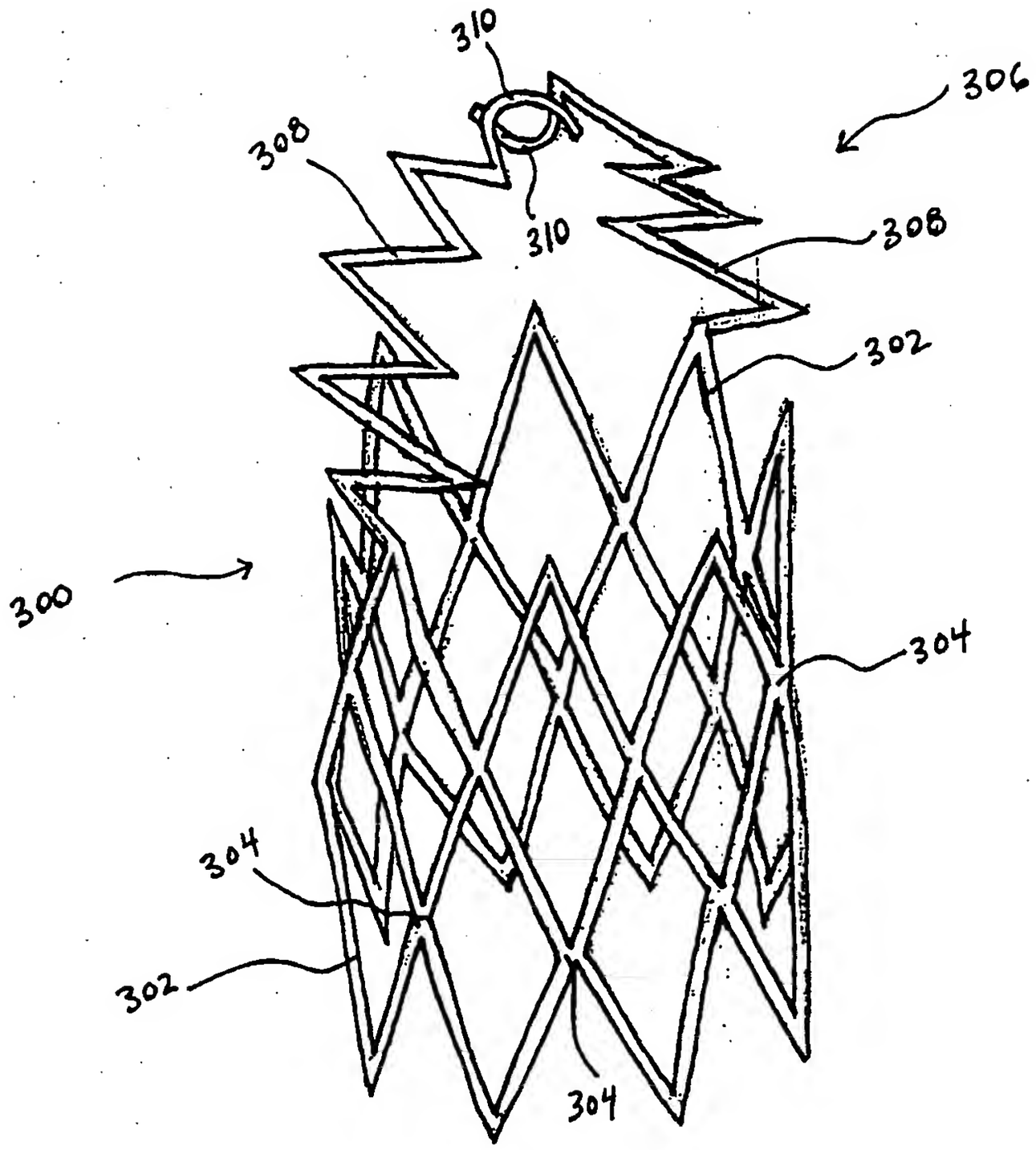


FIG. 22

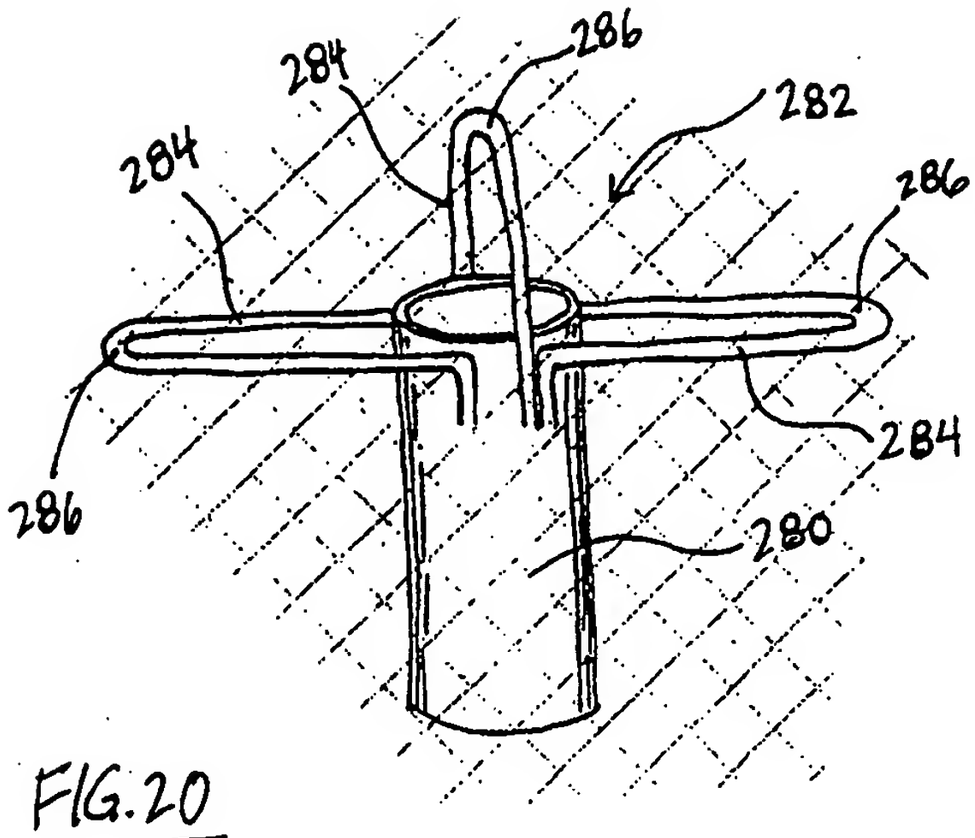


FIG. 20

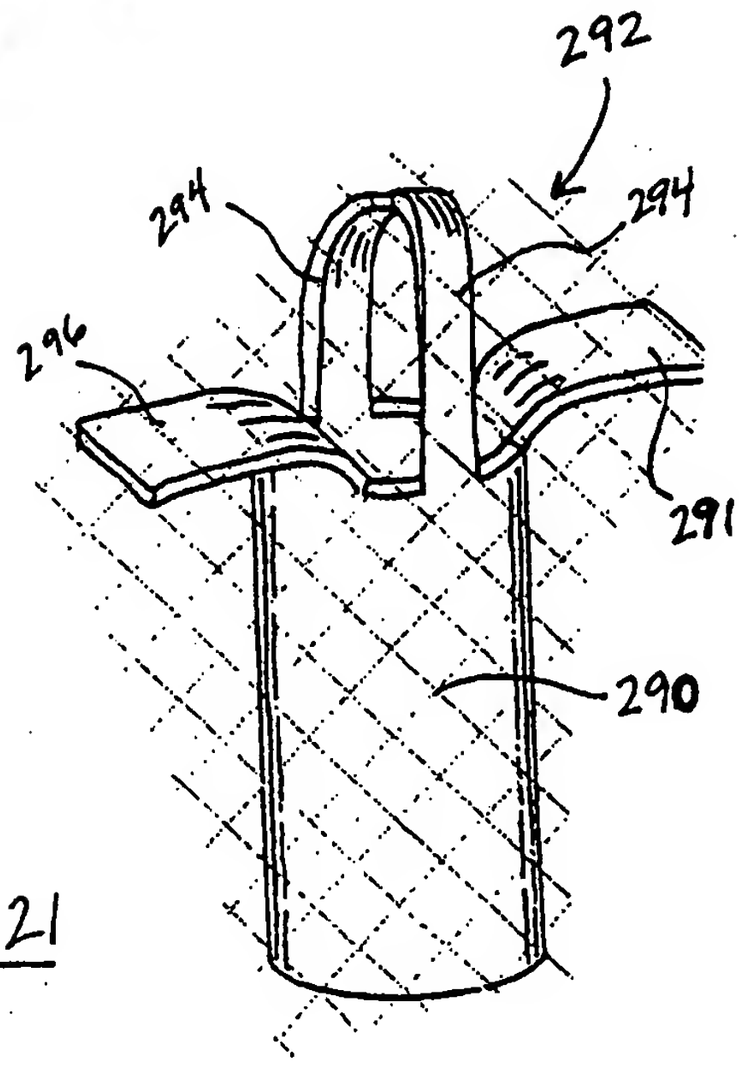


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/22954

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06
US CL :128/898

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/897, 898; 606/191, 194, 195; 623/001, 002

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,922,019 A (HANKH et al.) 13 July 1999, entire document.	1-46
A	US 5,922,022 A (NASH et al.) 13 July 1999, entire document.	1-46
A	US 5,976,178 A (GOLDSTEEN et al.) 02 November 1999, entire document.	1-46
A	US 5,829,447 A (STEVENS et al.) 03 November 1998, entire document.	1-46
Y	US 5,807,243 A (VIERRA et al.) 15 September 1998, entire document.	1-46
Y	US 5,782,746 A (WRIGHT) 21 July 1998, entire document.	1-46

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Date of the actual completion of the international search	Date of mailing of the international search report
31 JANUARY 2000	29 FEB 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer SAMUEL GILBERT Telephone No. (703) 308-3553

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CORRECTED VERSION*

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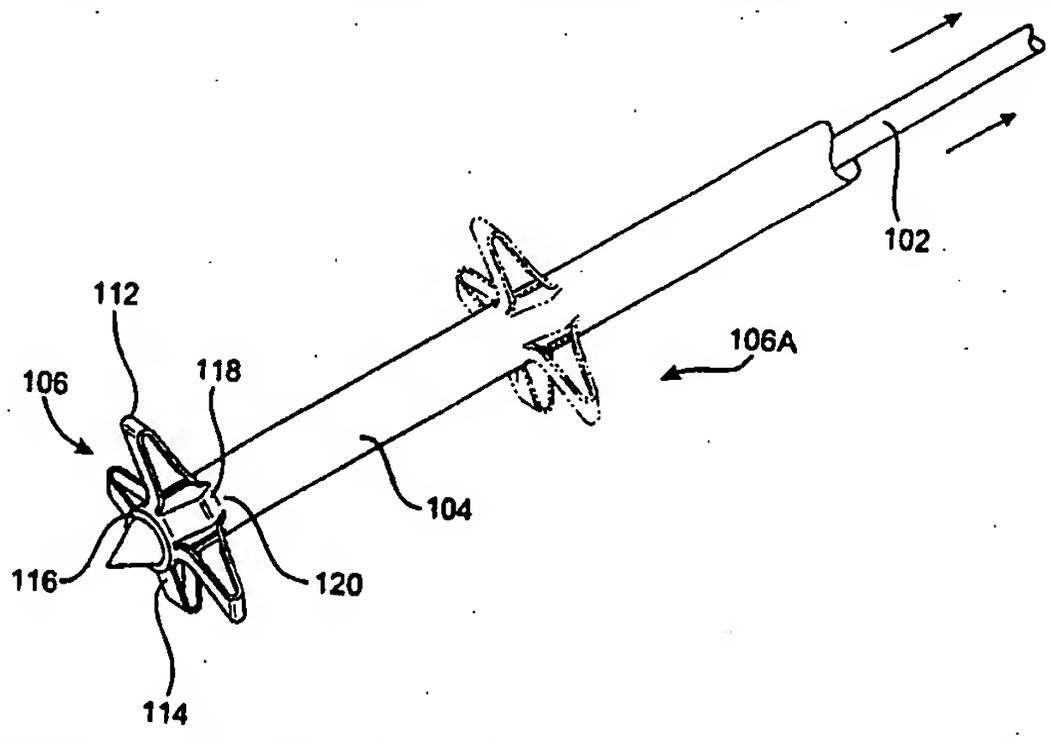
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: DEVICES AND METHODS FOR USE IN PERFORMING TRANSMYOCARDIAL CORONARY BYPASS



(57) Abstract

This invention is a trans–myocardial bypass device including retractors (R) used to engage, to support myocardial tissue, and mechanisms (100) for supporting coronary vessels so as to allow precise entry into a vessel lumen. Conduits (240) are provided having a configuration that permits positioning in a heart wall to place a coronary vessel in communication with a heart chamber.

*(Referred to in PCT Gazette No. 38/2000, Section II)

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DEVICES AND METHODS FOR USE IN PERFORMING TRANSMYOCARDIAL CORONARY BYPASS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to treating heart disease, and more particularly systems, devices and methods for reestablishing or improving blood flow to the myocardium.

2. Description of the Background Art

Despite the considerable advances that have been realized in cardiology and cardiovascular surgery, heart disease remains the leading cause of death throughout much of the world. Coronary artery disease, or arteriosclerosis, is the single leading cause of death in the United States today. As a result, those in the cardiovascular field continue the search for new and improved treatments.

Coronary artery disease is currently treated by interventional procedures such as percutaneous transluminal coronary angioplasty (PTCA), atherectomy and intracoronary stenting, as well as surgical procedures including coronary artery bypass grafting (CABG). The goal of these procedures is to reestablish or improve blood flow through occluded (or partially occluded) coronary arteries, which is accomplished, for example, by enlarging the blood flow lumen of the artery or by forming a bypass that allows blood to circumvent the occlusion. What procedure(s) is used typically depends on the severity and location of the blockages. When successful, these procedures restore blood flow to myocardial tissue that had not been sufficiently perfused due to the occlusion.

Technological and procedural advances have improved the results obtained by the medical procedures now used to treat heart disease, and in particular coronary artery disease. There is, however, still much room for improvement. For that reason there remains a need in the art for new and improved systems, devices and methods for treating heart disease such as arteriosclerosis.

SUMMARY OF THE INVENTION

In one embodiment, the invention provides a device and method for engaging tissue of a coronary vessel or heart wall during a cardiovascular procedure. A

device constructed according to this embodiment includes first and second members coupled together so as to permit relative movement. A tissue engaging mechanism is coupled to the first and second members and moves between first and second positions. In the preferred embodiment, the first and second positions are collapsed and expanded orientations. The tissue engaging mechanism includes at least one tissue engaging member that contacts engage body tissue when in the expanded orientation.

A method carried out according to this embodiment includes steps of providing a tissue support device having a tissue engaging mechanism configured to assume an expanded, tissue supporting orientation, positioning the tissue support device through the wall of a patient's heart and locating the tissue engaging mechanism adjacent tissue, and placing the tissue engaging mechanism in the expanded, tissue supporting orientation in engagement with the tissue.

In another embodiment, the invention provides a device and method for supporting a wall of a vascular structure in order to access the lumen of the vascular structure. A device constructed according to this embodiment includes a support structure adapted to be positioned in the lumen of a vascular structure, the support structure comprising a plurality of support elements coupled together so as to be movable relative to each other. The support elements move relative to each other to move the support structure from a collapsed orientation to an expanded orientation in order to support a wall of a vascular structure, and are sized and configured so that when the support structure is in the expanded orientation the support elements engage the wall of the vascular structure to prevent the wall from collapsing.

Another device constructed according to this embodiment includes an introducer having a hollow interior and an elongated support member configured to be generally coiled when in an unbiased orientation and generally straight when in a biased orientation. The interior of the introducer is sized and configured to receive the elongated support member and hold the support member in the generally straight, biased orientation. The elongated support member is moved from the straight, biased orientation within the interior of the introducer to the coiled, unbiased orientation upon entering the interior of the vascular structure to support the vascular structure.

A method carried out according to this embodiment includes steps of positioning a support within an interior of a vascular structure such that the support contacts and supports a wall of the vascular structure, and introducing a medical device

into the interior of the vascular structure by passing the device through the wall of the vascular structure and through the support.

In another embodiment, the invention provides a device and method for stabilizing an area of a patient's heart adjacent a coronary vessel. A device constructed according to this embodiment includes a base configured to be positioned adjacent a coronary vessel of a patient's heart, the base having at least one opening for accessing the coronary vessel. At least one tissue engaging element is coupled to the base so as to be movable with respect to the base, the tissue engaging element having a portion configured to securely engage the wall of a patient's heart in order to stabilize the wall of the heart upon moving the tissue engaging element with respect to the base. An actuator is provided for imparting relative movement to the base and the tissue engaging element in order to stabilize the heart while accessing the coronary vessel through the opening in the base.

In yet another embodiment, the invention provides a conduit for placing a coronary vessel of a patient's heart in communication with a heart chamber. The conduit is in the form of a tubular element including first and second portions having different cross-sectional sizes and a bore defining a blood flow path. The cross-section of the first portion of the tubular element is larger than the cross-section of the second portion such that the tubular element is generally funnel-shaped, and the first and second portions of the tubular element are generally aligned so that the bore defines a generally straight blood flow path.

In still another embodiment, the invention provides a conduit for communicating a chamber of a patient's heart with a coronary vessel. The conduit is in the form of an expandable stent including first and second portions having different cross-sectional sizes when the stent is expanded. Each of the first and second portions of the stent includes strut members disposed along a first direction when the stent is unexpanded and along a second direction when the stent is expanded, the second direction being transverse to the first direction. The strut members of the first portion are longer than the strut members of the second portion so that the stent is generally funnel-shaped when expanded.

In another embodiment, the invention provides a conduit is in the form of an expandable tubular element having first and second portions with different cross-sectional sizes. This tubular element is preferably a coronary stent constructed so that the

first and second portions are disposed in an orientation that provides the stent with maximum radial strength when expanded.

In a final embodiment, the invention provides a conduit for placing a coronary vessel in communication with a heart chamber, the conduit including a vessel support mechanism configured to contact and support the vessel wall when the conduit is positioned in the heart wall.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood from the following detailed description of preferred embodiments thereof, taken in conjunction with the accompanying drawing figures, wherein:

Fig. 1 is a schematic view of a patient prepared to undergo a cardiovascular surgical procedure, the patient's heart being exposed via a retractor positioned in a thoracotomy formed in the patient's chest;

Fig. 2 is a perspective view of the heart shown in Fig. 1, wherein a portion of the heart wall is broken away for clarity;

Fig. 2A is an enlarged view of a portion of Fig. 2;

Figs. 3A-3B are perspective views showing a tissue engaging device constructed according to one embodiment of the invention, the device being shown in collapsed and expanded orientations, respectively;

Figs. 4A-4B are elevation views, in section, illustrating one preferred construction of a tissue engaging device according to the embodiment of Figs. 3A-3B, wherein the device is shown being used to engage the heart wall shown in Figs. 2-2A;

Figs. 5A-5B are elevation views, in section, illustrating another preferred construction of a tissue engaging device according to the embodiment of Figs. 3A-3B, wherein the device is shown being used to engage the heart wall shown in Figs. 2-2A;

Figs. 6A-6C are elevation views, in section, sequentially illustrating a vessel support device constructed according to another embodiment of the invention being used to support the wall of a vascular structure;

Fig. 7 is a perspective view of a vessel support device constructed according to an alternative embodiment of the invention, the device being shown positioned in the interior of a vascular structure;

Figs. 8A-8B are elevation views, in section, sequentially illustrating the device shown in Fig. 7 being used to support a coronary artery of the heart shown in Figs. 2-2A;

Fig. 9 is a perspective view of a vessel support device constructed according to another alternative embodiment of the invention, the device being shown positioned in the interior of a vascular structure;

Figs. 10A-10B are elevation views, in section, sequentially illustrating the device shown in Fig. 9 being used to support a coronary artery of the heart shown in Figs. 2-2A;

Figs. 11A-11B are plan views of a tissue engaging device constructed according to another embodiment of the invention, wherein the device is shown engaging the wall of the heart shown in Figs. 2-2A in non-retracting and retracting orientations, respectively;

Figs. 12A-12B are elevation views, in section, taken along lines A-A in Figs. 11A-11B;

Fig. 13 is an elevation view, in section, of an alternative tissue engaging device constructed according to the embodiment shown in Figs. 12A-12B;

Figs. 14A-14B are elevation views of a tapered balloon forming part of another embodiment of the invention, wherein the balloon is shown in its collapsed and expanded orientations, respectively;

Figs. 15A-15B are elevation views of an expandable conduit mounted on the tapered balloon shown in Figs. 14A-14B, the conduit being shown in its collapsed and expanded orientations, respectively;

Fig. 16 is an elevation view, in section, of a portion of a heart wall and coronary vessel in which the conduit shown in Fig. 15A-15B has been positioned;

Figs. 17A-17B are elevation views showing a conduit constructed according to still another embodiment of the invention, wherein the conduit has a cross-sectional size that varies over its length;

Fig. 18 is a perspective view of another embodiment of the invention providing a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel;

Figs. 19A-19C are schematic representations of a preferred application for the conduit shown in Fig. 18;

Fig. 20 is a perspective view of an alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel;

Fig. 21 is a perspective view of another alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel; and

Fig. 22 is a perspective view of yet another alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The invention will be better understood from the following detailed description of preferred embodiments thereof, taken in conjunction with the accompanying drawing figures, wherein:

Fig. 1 is a schematic view of a patient prepared to undergo a cardiovascular surgical procedure, the patient's heart being exposed via a retractor positioned in a thoracotomy formed in the patient's chest;

Fig. 2 is a perspective view of the heart shown in Fig. 1, wherein a portion of the heart wall is broken away for clarity;

Fig. 2A is an enlarged view of a portion of Fig. 2;

Figs. 3A-3B are perspective views showing a tissue engaging device constructed according to one embodiment of the invention, the device being shown in collapsed and expanded orientations, respectively;

Figs. 4A-4B are elevation views, in section, illustrating one preferred construction of a tissue engaging device according to the embodiment of Figs. 3A-3B, wherein the device is shown being used to engage the heart wall shown in Figs. 2-2A;

Figs. 5A-5B are elevation views, in section, illustrating another preferred construction of a tissue engaging device according to the embodiment of Figs. 3A-3B, wherein the device is shown being used to engage the heart wall shown in Figs. 2-2A;

Figs. 6A-6C are elevation views, in section, sequentially illustrating a vessel support device constructed according to another embodiment of the invention being used to support the wall of a vascular structure;

Fig. 7 is a perspective view of a vessel support device constructed according to an alternative embodiment of the invention, the device being shown positioned in the interior of a vascular structure;

Figs. 8A-8B are elevation views, in section, sequentially illustrating the device shown in Fig. 7 being used to support a coronary artery of the heart shown in Figs. 2-2A;

Fig. 9 is a perspective view of a vessel support device constructed according to another alternative embodiment of the invention, the device being shown positioned in the interior of a vascular structure;

Figs. 10A-10B are elevation views, in section, sequentially illustrating the device shown in Fig. 9 being used to support a coronary artery of the heart shown in Figs. 2-2A;

Figs. 11A-11B are plan views of a tissue engaging device constructed according to another embodiment of the invention, wherein the device is shown engaging the wall of the heart shown in Figs. 2-2A in non-retracting and retracting orientations, respectively;

Figs. 12A-12B are elevation views, in section, taken along lines A-A in Figs. 11A-11B;

Fig. 13 is an elevation view, in section, of an alternative tissue engaging device constructed according to the embodiment shown in Figs. 12A-12B;

Figs. 14A-14B are elevation views of a tapered balloon forming part of another embodiment of the invention, wherein the balloon is shown in its collapsed and expanded orientations, respectively;

Figs. 15A-15B are elevation views of an expandable conduit mounted on the tapered balloon shown in Figs. 14A-14B, the conduit being shown in its collapsed and expanded orientations, respectively;

Fig. 16 is an elevation view, in section, of a portion of a heart wall and coronary vessel in which the conduit shown in Fig. 15A-15B has been positioned;

Figs. 17A-17B are elevation views showing a conduit constructed according to still another embodiment of the invention, wherein the conduit has a cross-sectional size that varies over its length;

Fig. 18 is a perspective view of another embodiment of the invention providing a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel;

Figs. 19A-19C are schematic representations of a preferred application for the conduit shown in Fig. 18;

Fig. 20 is a perspective view of an alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel;

Fig. 21 is a perspective view of another alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel; and

Fig. 22 is a perspective view of yet another alternative embodiment of a conduit for placing a coronary vessel in communication with a heart chamber while internally supporting the interior of the vessel.

WHAT IS CLAIMED IS:

1. A device for engaging tissue of a coronary vessel or heart wall during a cardiovascular procedure, the device comprising:

a first member;

a second member coupled to the first member so as to permit relative movement of the first and second members; and

a tissue engaging mechanism coupled to the first and second members so as to be movable between a first position and a second, actuated position, the tissue engaging mechanism including at least one tissue engaging member configured to engage body tissue when the tissue engaging mechanism is in the second actuated position;

wherein relative movement of the first and second members moves the tissue engaging mechanism between the collapsed and expanded orientations to selectively place the tissue engaging member in engagement with body tissue.

2. The device of claim 1, wherein the first and second members are first and second coaxial shafts with the tissue engaging mechanism extending therebetween, and relative axial movement of the first and second shafts moves the tissue engaging mechanism between a collapsed orientation and an expanded orientation.

3. The device of claim 2, wherein each of the first and second shafts has a proximal end and a distal end, and the tissue engaging mechanism is disposed adjacent the distal ends of the shafts.

4. The device of claim 3, wherein at least one of the first and second shafts has a portion configured to be passed through and dilate an opening in tissue, wherein the tissue engaging mechanism may be positioned adjacent tissue and then expanded to engage the tissue.

5. The device of claim 1, further comprising an actuator coupled to the first and second members for imparting relative movement thereto in order to move the tissue engaging mechanism between the collapsed and expanded orientations.

6. The device of claim 5, wherein the actuator comprises a handle coupled to one of the first and second members for moving the one member relative to the other member.

7. The device of claim 1, wherein the tissue engaging mechanism includes a non-inflatable structure that is moved between the collapsed and expanded orientations.

8. The device of claim 1, wherein the tissue engaging mechanism includes a plurality of tissue engaging members each of which has opposite ends coupled, respectively, to the first and second members, wherein relative movement of the first and second members imparts relative movement to the ends of the tissue engaging members to move the tissue engaging mechanism between the collapsed and expanded orientations.

9. The device of claim 1, wherein the tissue engaging mechanism includes a balloon that is inflated by pressurized fluid to engage the tissue.

10. The device of claim 1, wherein the tissue engaging mechanism includes an expandable mesh that is moved between the collapsed and expanded orientations in response to relative movement of the first and second members.

11. The device of claim 1, wherein first and second tissue engaging mechanisms are coupled to the first and second members so that each mechanism is movable between a collapsed orientation and an expanded orientation, the first and second tissue engaging mechanisms being spaced from each other to permit body tissue to be captured therebetween with the first and second tissue engaging mechanisms engaging opposite surfaces of the body tissue.

12. A method for supporting heart tissue during a medical procedure, the method comprising steps of:

providing a tissue support device having a tissue engaging mechanism configured to assume an expanded, tissue supporting orientation;

positioning the tissue support device through the wall of a patient's heart and locating the tissue engaging mechanism adjacent heart tissue; and

placing the tissue engaging mechanism in the expanded, tissue supporting orientation in engagement with the heart tissue.

13. The method of claim 12, further comprising positioning a conduit in the wall of the heart to place a coronary vessel in communication with a heart chamber.

14. A device for supporting a wall of a vascular structure, the device comprising:

a support structure adapted to be removably positioned in the lumen of a vascular structure, the support structure comprising a plurality of support elements coupled together so as to be movable relative to each other, wherein moving the support elements relative to each other moves the support structure from a collapsed orientation to an expanded orientation in order to support a wall of a vascular structure; and

wherein the support elements are sized and configured for positioning in the interior of the vascular structure such that when the support structure is in the expanded orientation the support elements engage the wall of the vascular structure to prevent the wall from collapsing.

15. The device of claim 14, wherein the support elements comprise a plurality of flexible struts each of which has a free end, wherein the free ends of the struts are moved apart to place the support structure in the expanded orientation.

16. The device of claim 15, further comprising a sheath coupled to the flexible struts so that movement of the sheath relative to the struts moves the free ends of the struts apart to place the support structure in the expanded orientation.

17. The device of claim 14, wherein the support elements comprise a plurality of flexible struts each of which has first and second ends and a central portion between the ends, wherein the first ends of the struts are fixed to each other and the second ends of the struts are fixed to each other such that the central portions of the struts move away from each other as the support structure moves to the expanded orientation.

18. The device of claim 16, further comprising a sheath slidable over the flexible struts, wherein the sheath is placed over at least a portion of the struts to move the support structure to the collapsed orientation and is removed from the said portion of the struts to move the support structure in the expanded orientation.

19. A device for supporting a vascular structure, the device comprising:

an introducer having a hollow interior;

an elongated support member configured to be generally coiled when in an unbiased orientation and generally straight when in a biased orientation;

wherein the interior of the introducer is sized and configured to receive the elongated support member and hold the support member in the generally straight, biased orientation; and

wherein the elongated support member is moved from the straight, biased orientation within the interior of the introducer to the coiled, unbiased orientation upon entering the interior of the vascular structure to support the vascular structure.

20. The device of claim 19, wherein the elongated support member is a superelastic wire that is generally straight when in the biased orientation and generally helical when in the unbiased orientation.

21. The device of claim 20, wherein an end of the elongated support member is sharpened for forming an opening in the wall of the vascular structure to pass the support member into the interior of the vascular structure.

22. The device of claim 19, wherein the elongated support member is adapted to be removed from the vascular structure via the opening through which the support member is passed into the vascular structure.

23. A method for internally supporting a wall of a vascular structure, the method comprising steps of:

(a) positioning a support within an interior of a vascular structure such that the support contacts and supports a wall of the vascular structure; and

(b) introducing a medical device into the interior of the vascular structure by passing the device through the wall of the vascular structure and through the support.

24. The method of claim 23, wherein the support is an elongated member configured in a generally straight orientation prior to being positioned in the interior of the vascular structure and assumes a generally coiled orientation once positioned in the interior of the vascular structure, the medical device being introduced between coils of the support into the vascular structure.

25. The method of claim 23, wherein the support is movable between collapsed and expanded orientations, and step (a) is carried out by introducing the support

into the vascular structure in said collapsed orientation and then moving the support to said expanded orientation.

26. The method of claim 23, wherein the support comprises a sleeve having at least one opening formed therein through which the medical device is introduced.

27. The method of claim 23, wherein the vascular structure is a coronary artery and the medical device is a conduit delivery device that is passed through the coronary artery to position a conduit in the wall of the heart to communicate the coronary artery with a heart chamber.

28. The method of claim 23, further comprising the step of removing the medical device and the support from the vascular structure.

29. A method for supporting a wall of a vascular structure at an area adjacent an incision in the wall of the vascular structure, the method comprising steps of:

inserting a support through the incision in the wall of the vascular structure while the support is in a low profile orientation;

positioning at least a portion of the support within the interior of the vascular structure; and

moving the support from the low profile orientation into an expanded orientation so as to contact and support the wall of the vascular structure.

30. The method of claim 29, further comprising introducing a medical device into the interior of the vascular structure by passing the device through the support.

31. The method of claim 30, wherein the vascular structure is a coronary artery and the medical device is a conduit delivery device that is passed through the coronary artery to position a conduit in the wall of the heart to communicate the coronary artery with a heart chamber.

32. A device for stabilizing an area of a patient's heart adjacent a coronary vessel, the device comprising:

a base configured to be positioned adjacent a coronary vessel of a patient's heart, the base having at least one opening for accessing the coronary vessel;

at least one tissue engaging element coupled to the base so as to be movable with respect to the base, the tissue engaging element having a portion configured to securely engage the wall of a patient's heart in order to stabilize the wall of the heart upon moving the tissue engaging element with respect to the base; and

an actuator for imparting relative movement to the base and the tissue engaging element in order to stabilize the heart while accessing the coronary vessel through the opening in the base.

33. The device of claim 32, wherein the base has a single opening for accessing the coronary vessel and a plurality of tissue engaging elements are coupled to the base.

34. The device of claim 33, wherein the tissue engaging elements comprise legs each of which has one end pivotally attached to the base and another end provided with a member configured to at least partially penetrate the wall of the heart.

35. The device of claim 34, wherein the base has a plurality of recesses each of which pivotally mounts the one end of one of the legs, each recess having a cam surface that moves the leg with respect to the base when the base is rotated.

36. The device of claim 32, wherein the tissue engaging elements include a sharpened end configured to partially penetrate the wall of the heart.

37. The device of claim 36, wherein each tissue engaging element has an end provided with an expandable member, the expandable member configured to be passed through the wall of the heart to a location adjacent a surface of the wall opposite the coronary vessel and then expanded to engage said surface of the wall.

38. A conduit for placing a coronary vessel of a patient's heart in communication with a heart chamber, the conduit comprising:

a tubular element including first and second portions having different cross-sectional sizes, the tubular element having a bore defining a blood flow path;

wherein the cross-section of the first portion of the tubular element is larger than the cross-section of the second portion of the tubular element such that the tubular element is generally funnel-shaped; and

wherein the first and second portions of the tubular element are generally aligned and the bore defines a generally straight blood flow path.

39. A conduit for communicating a chamber of a patient's heart with a coronary vessel, the conduit comprising:

an expandable stent including first and second ends and a length defined between the ends, the length of the stent including first and second portions having different cross-sectional sizes when the stent is expanded;

wherein each of the first and second portions of the stent includes strut members disposed along a first direction when the stent is unexpanded and along a second direction when the stent is expanded, the second direction being transverse to the first direction; and

wherein the strut members of the first portion are longer than the strut members of the second portion and the stent is generally funnel-shaped when expanded.

40. A device for use in a coronary vessel of a patient's heart, the device comprising:

an expandable stent including a bore defining a blood flow path and first and second portions, the first and second portions having different cross-sectional sizes when the stent is expanded;

wherein the first portion has a larger cross-sectional dimension than the second portion when the stent is expanded such that the stent is generally funnel-shaped when expanded; and

wherein the first and second portions of the stent are constructed to provide the stent with maximum radial strength when expanded.

41. The device of claim 40, wherein the stent is configured to be positioned and retained in a heart wall to place a coronary vessel in communication with a heart chamber.

42. The device of claim 40, wherein the stent has a plurality of openings along the length of the stent through which blood may flow.

43. A method for placing a generally funnel-shaped conduit in a wall of a patient's heart to communicate a heart chamber with an interior of a coronary vessel located near the exterior of the heart, the method comprising steps of:

(a) providing a conduit having a length, a first end, and a second end, wherein the conduit is generally straight and the second end has a larger cross-section than the first end such that the conduit is generally funnel-shaped;

(b) positioning the conduit in the wall of the heart to communicate the heart chamber with the interior of the coronary vessel; and

(c) orienting the conduit in the wall of the heart such that the first end is disposed adjacent the coronary vessel and the second end is disposed adjacent the heart chamber.

44. A conduit for placing a coronary vessel of a patient's heart in communication with a heart chamber, the conduit comprising:

a tubular element configured to positioned in the wall of a patient's heart, the tubular element including first and second ends and a bore defining a blood flow path; and

a vessel supporting mechanism carried by the tubular element, the vessel supporting mechanism being positioned on the conduit so as to contact and support the wall of a coronary vessel when the conduit is positioned in the heart wall.

45. The conduit of claim 44, wherein the tubular element is a rigid, solid walled structure.

46. The conduit of claim 44, wherein the tubular element is an expandable stent including a plurality of struts, and the vessel supporting mechanism comprises some of the struts.

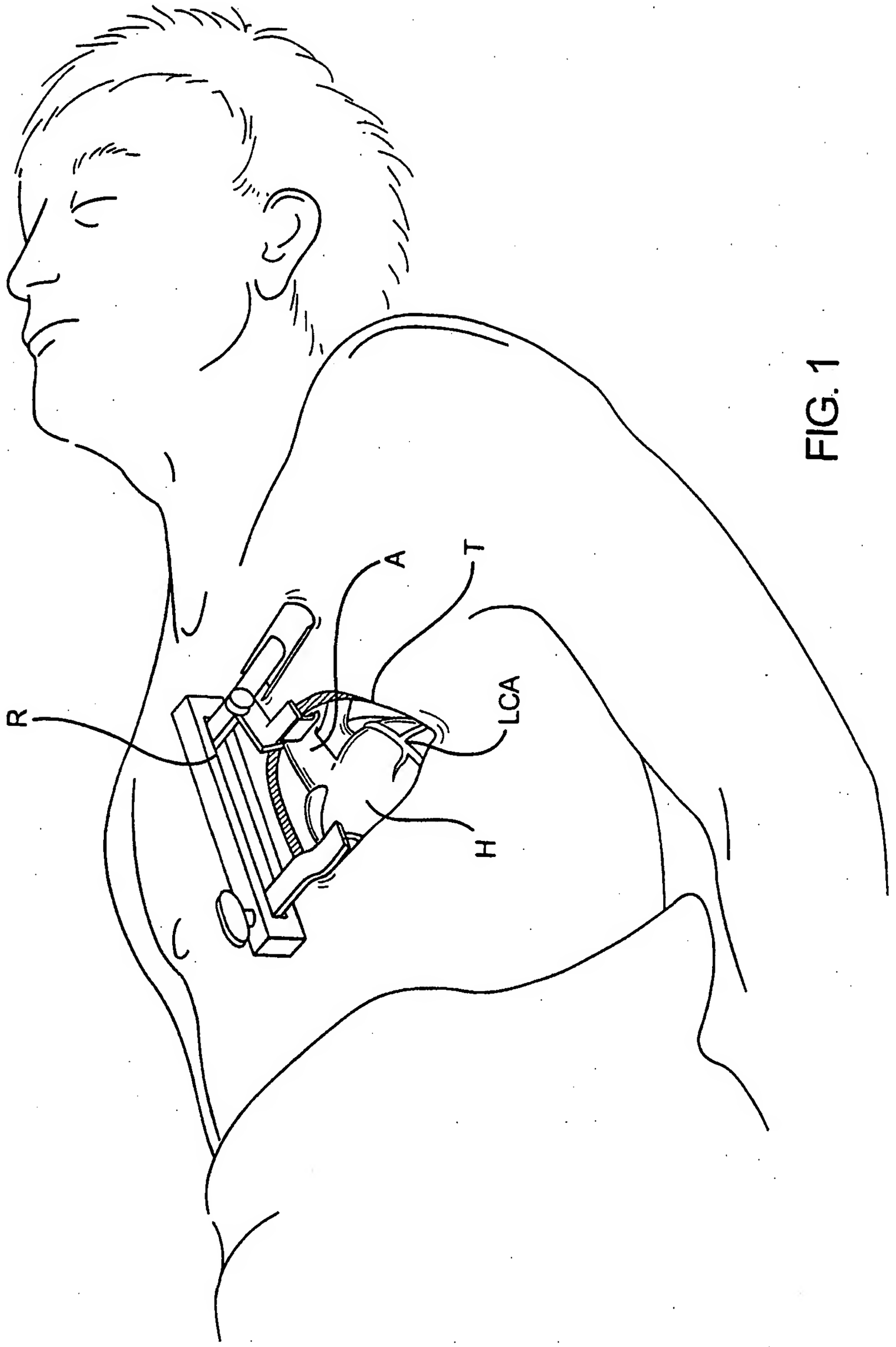


FIG. 1

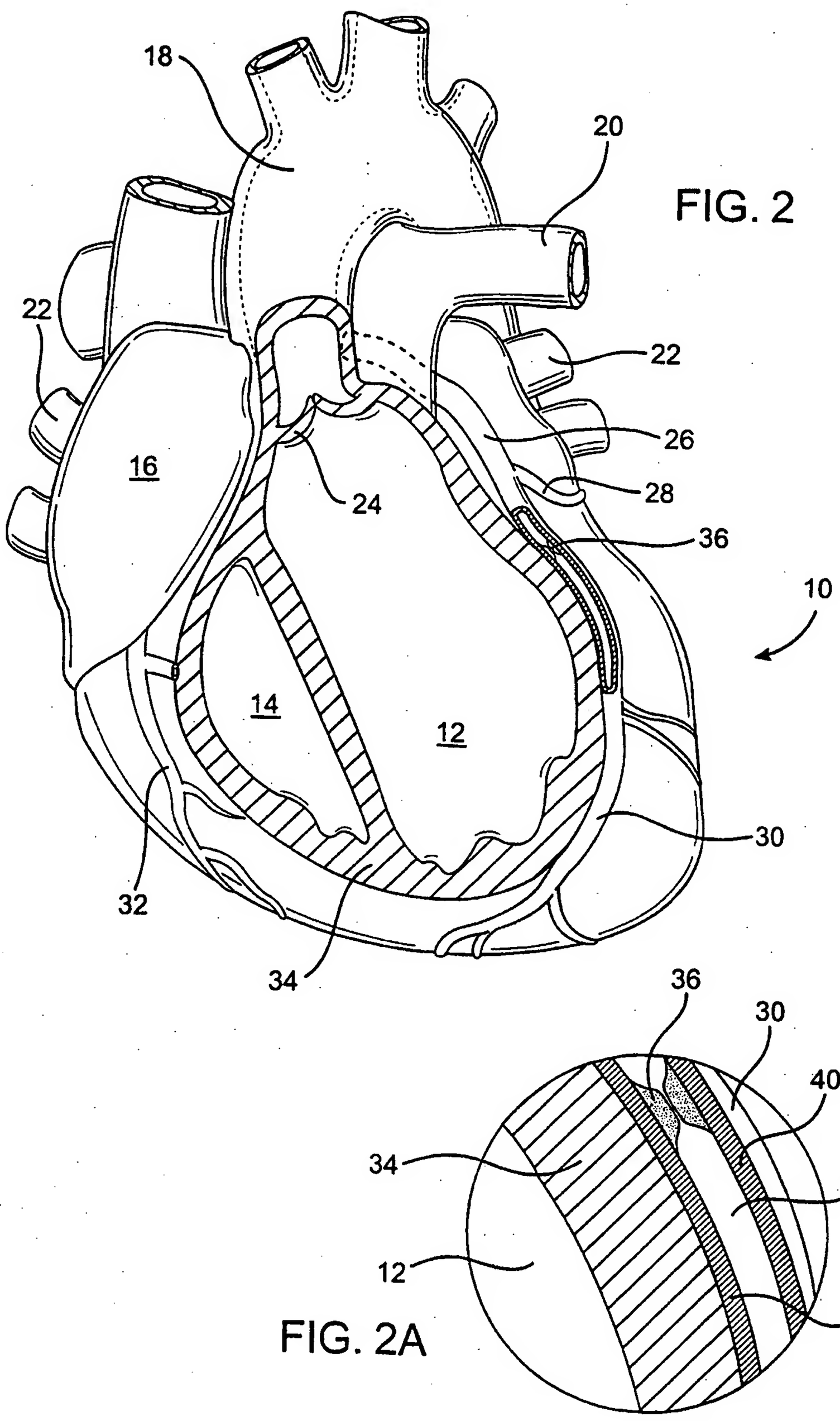
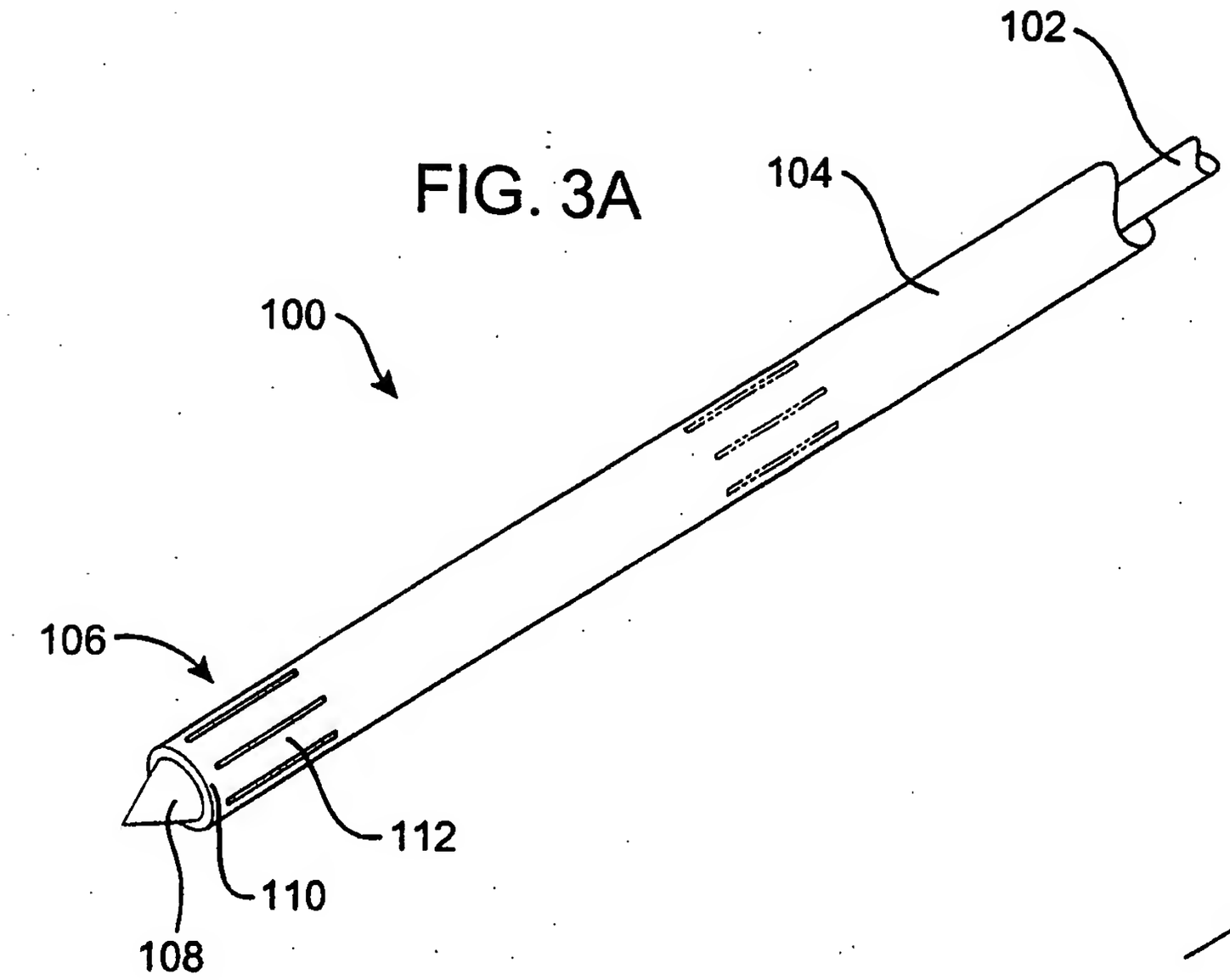


FIG. 2

FIG. 2A

FIG. 3A



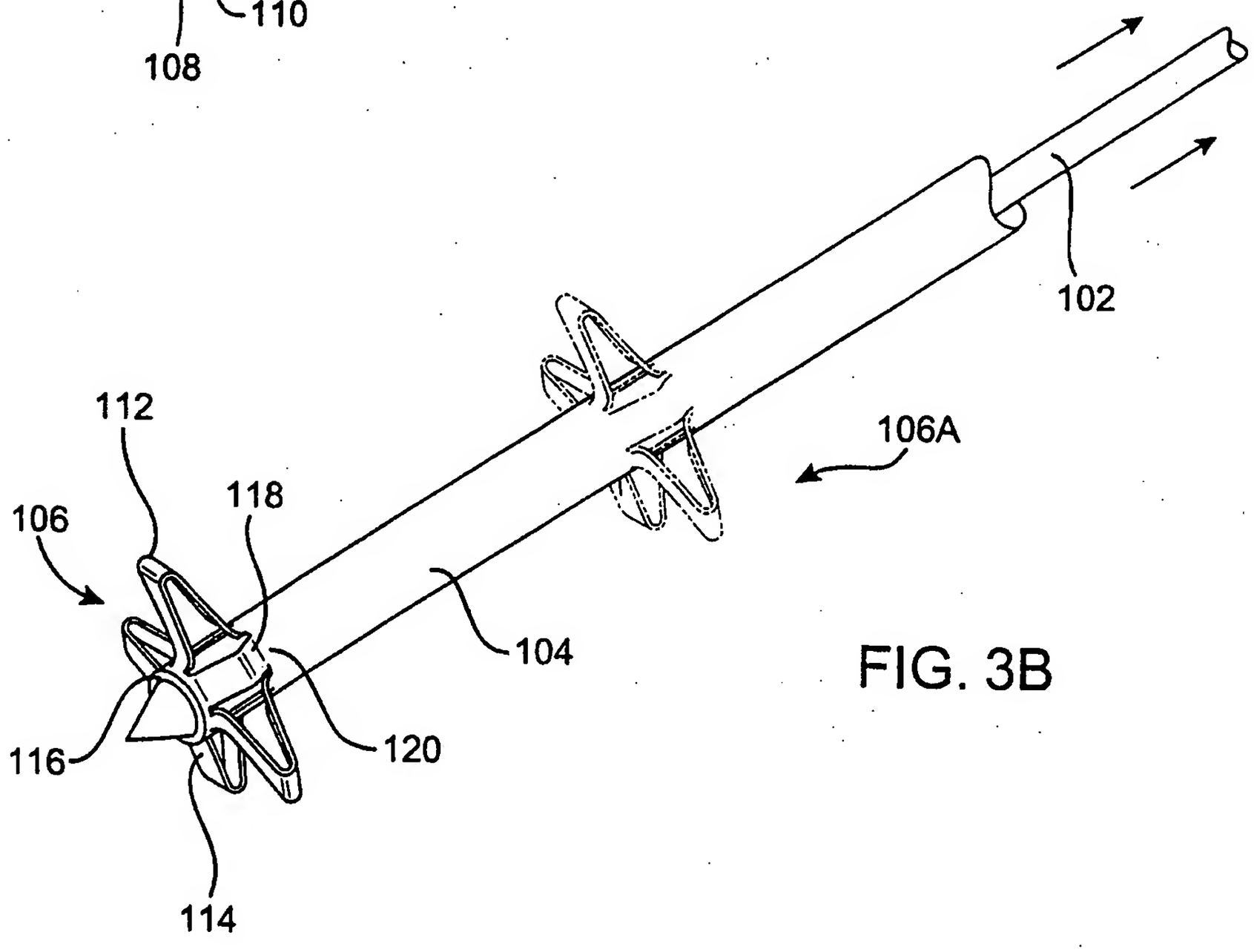


FIG. 3B

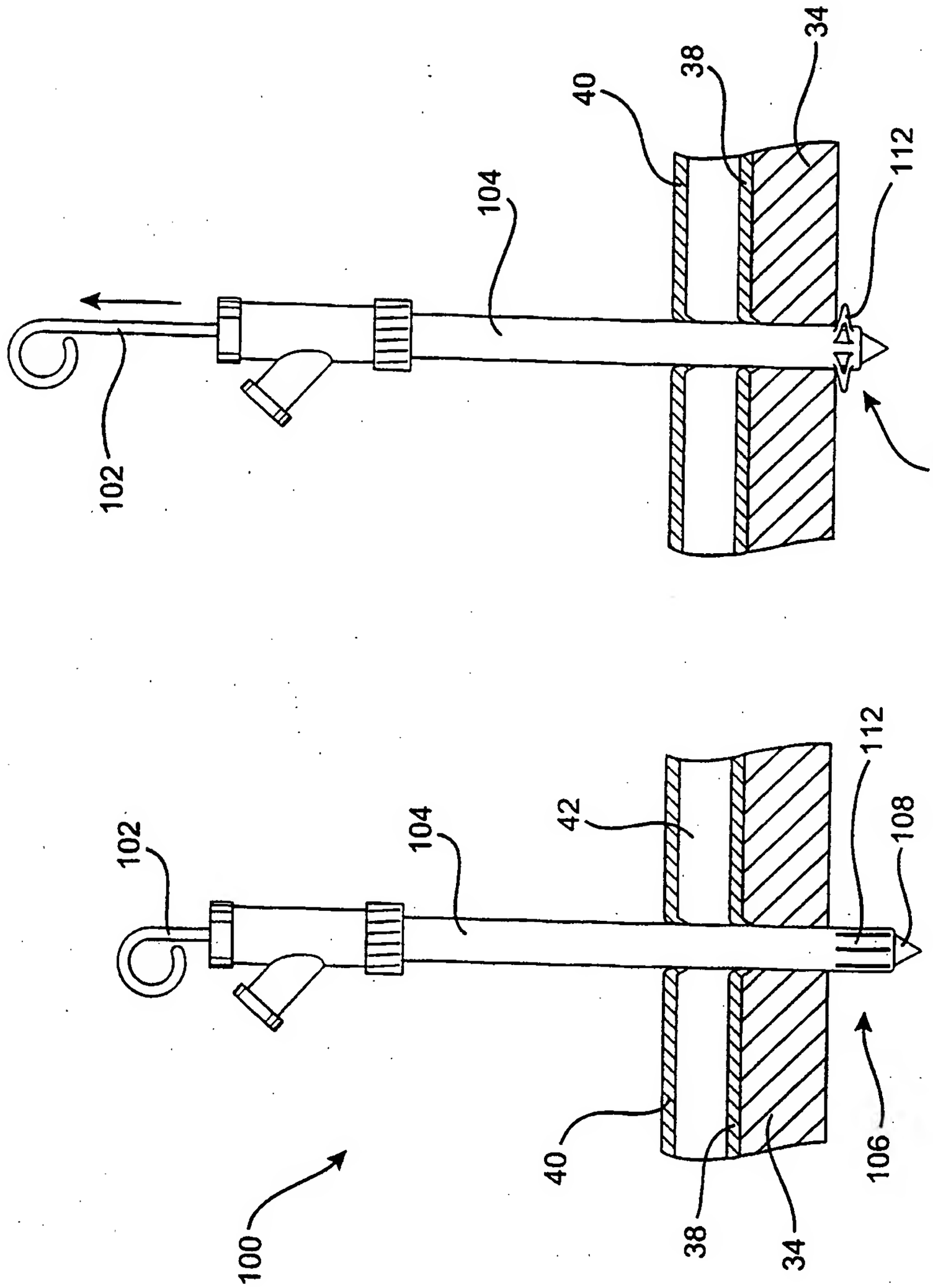


FIG. 4A

FIG. 4B

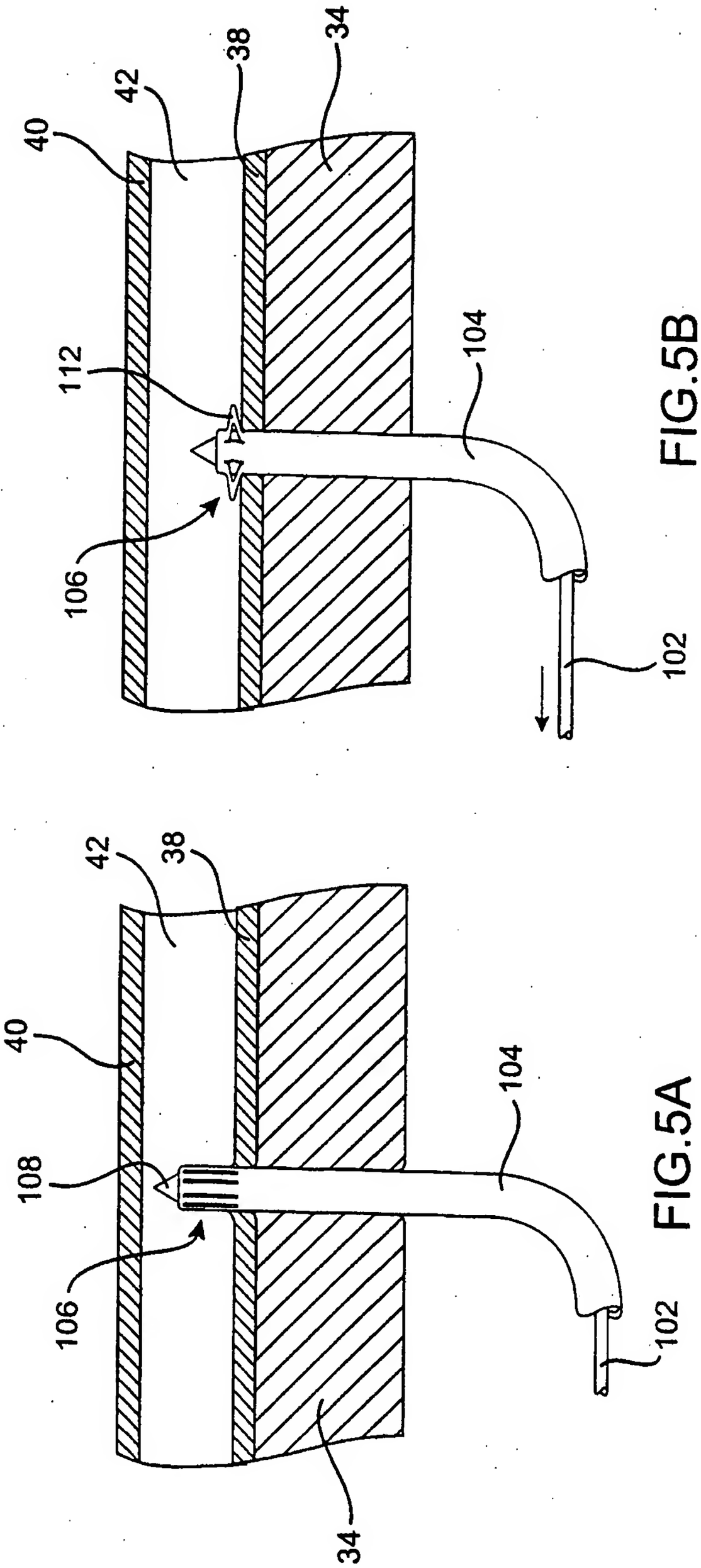


FIG.5B

FIG.5A

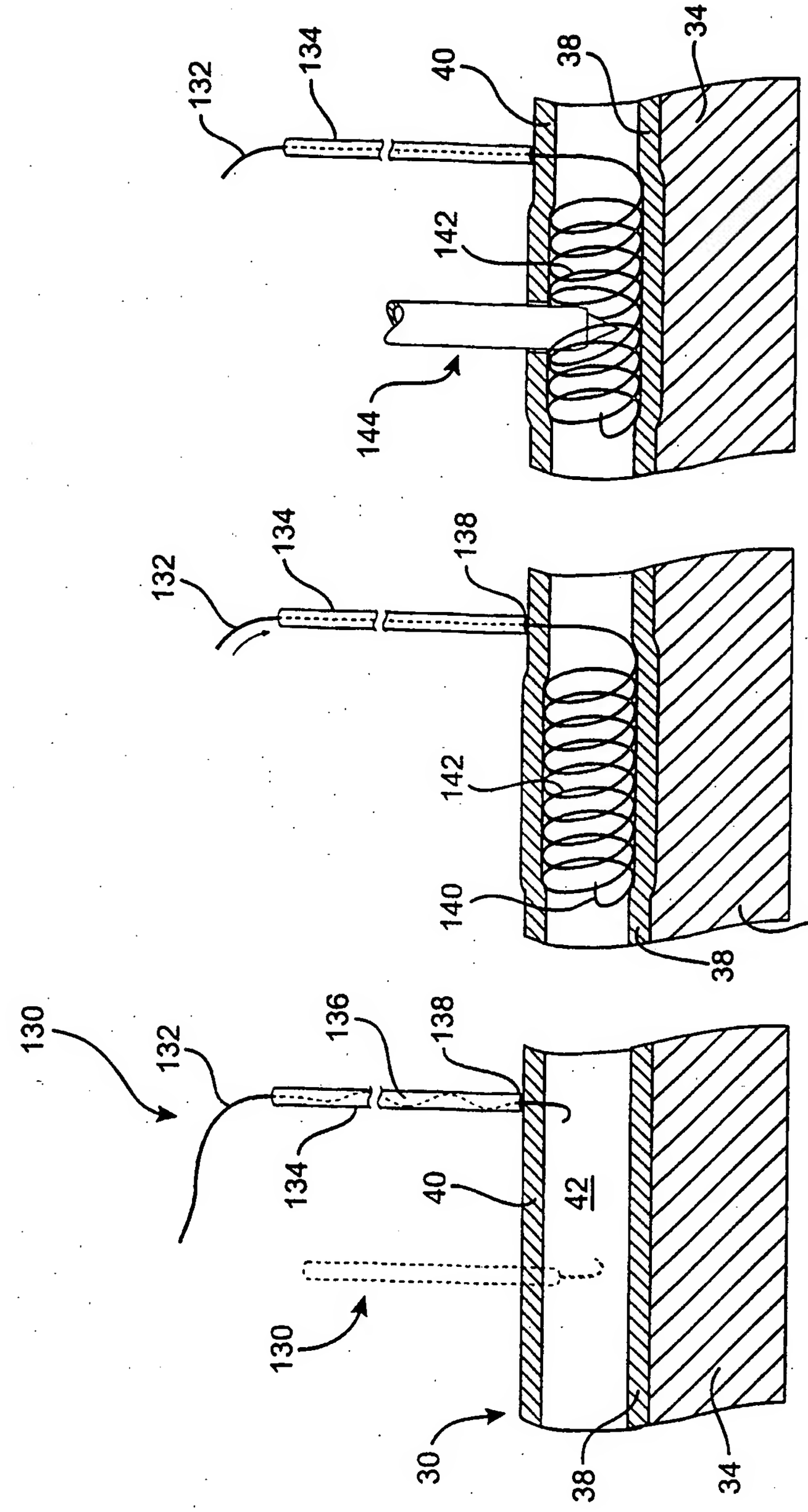


FIG. 6C

FIG. 6B

FIG. 6A

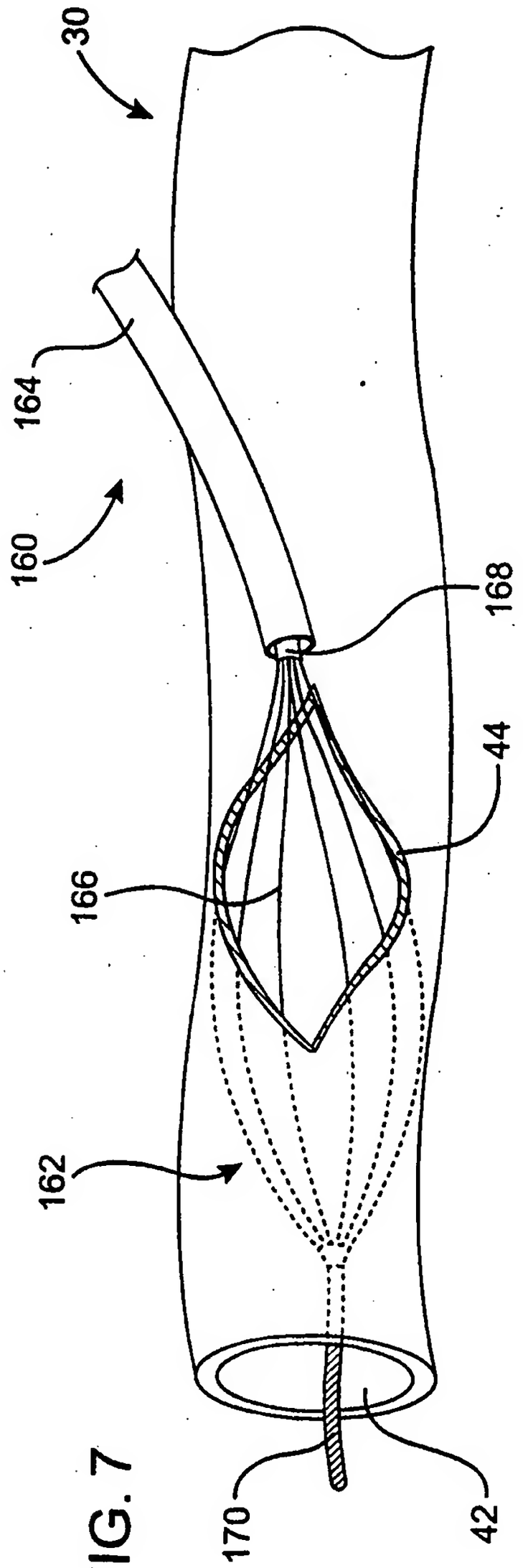


FIG. 7

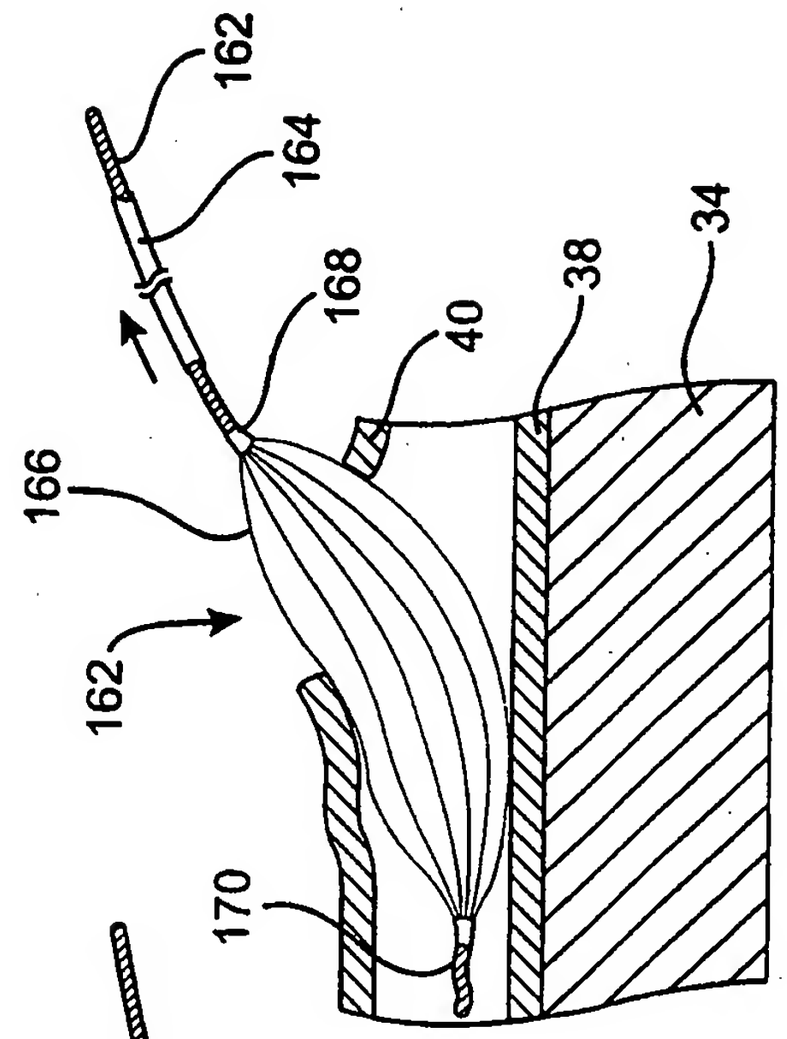


FIG. 8B

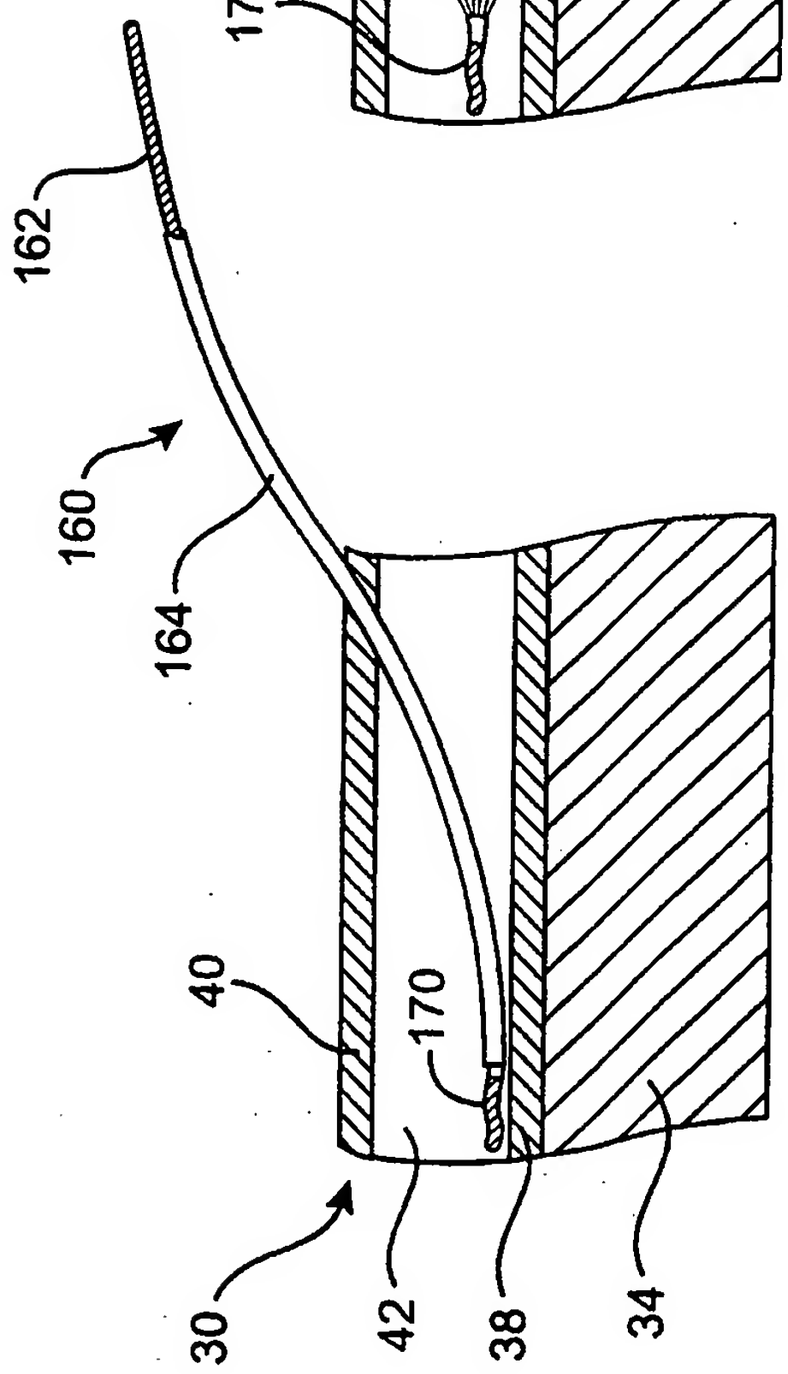


FIG. 8A

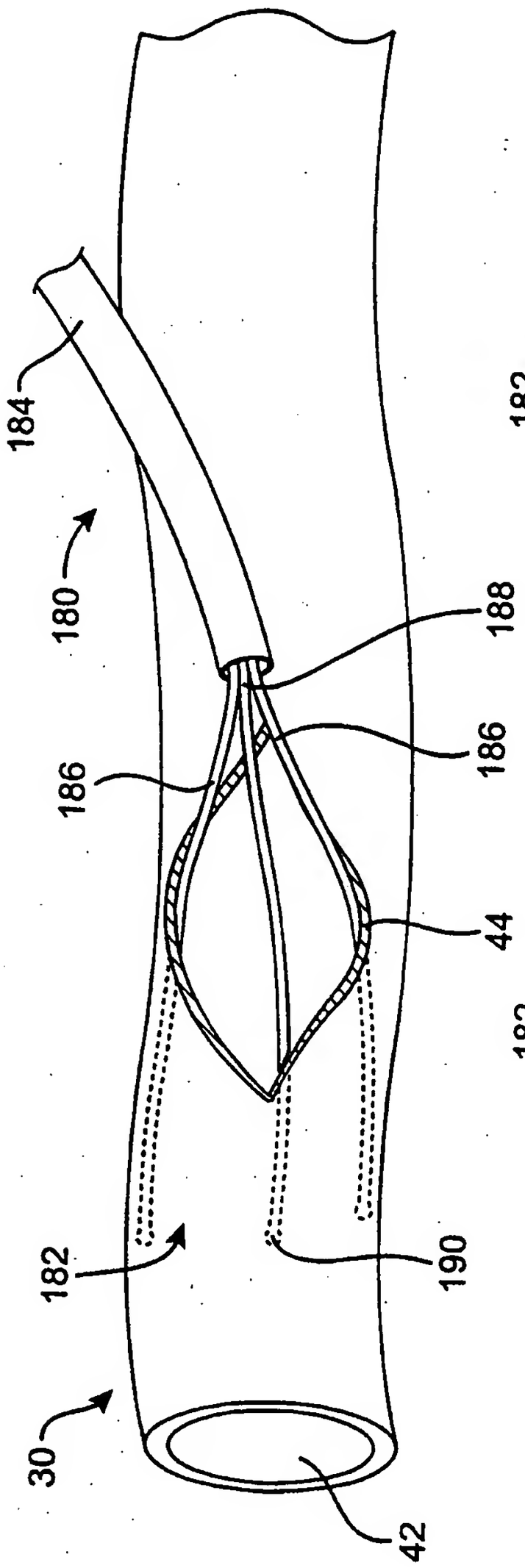


FIG. 9

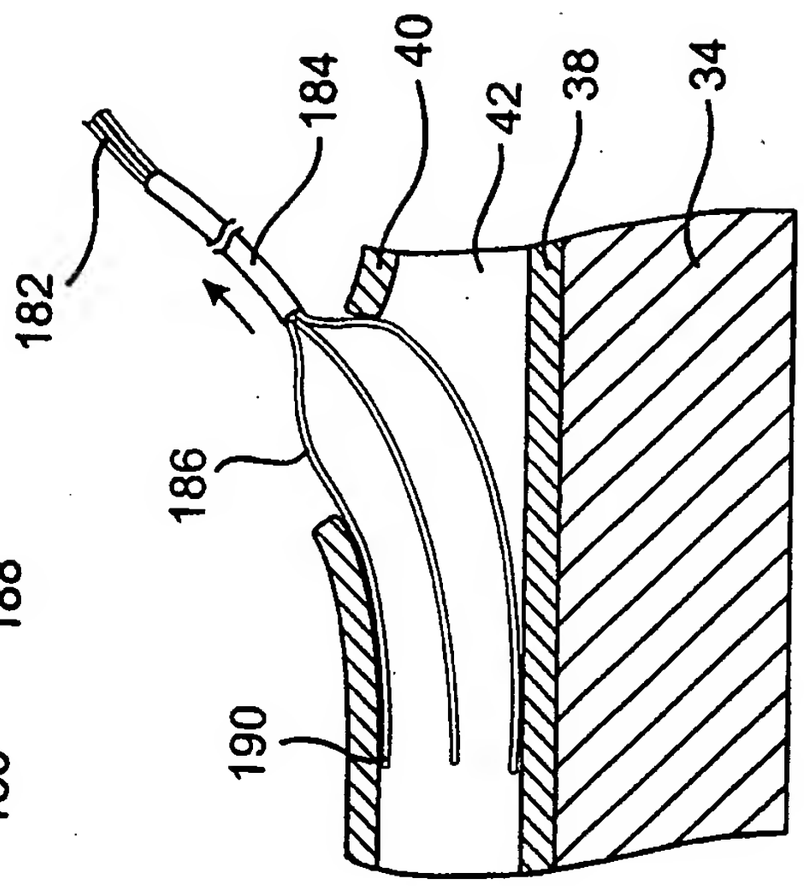


FIG.10B

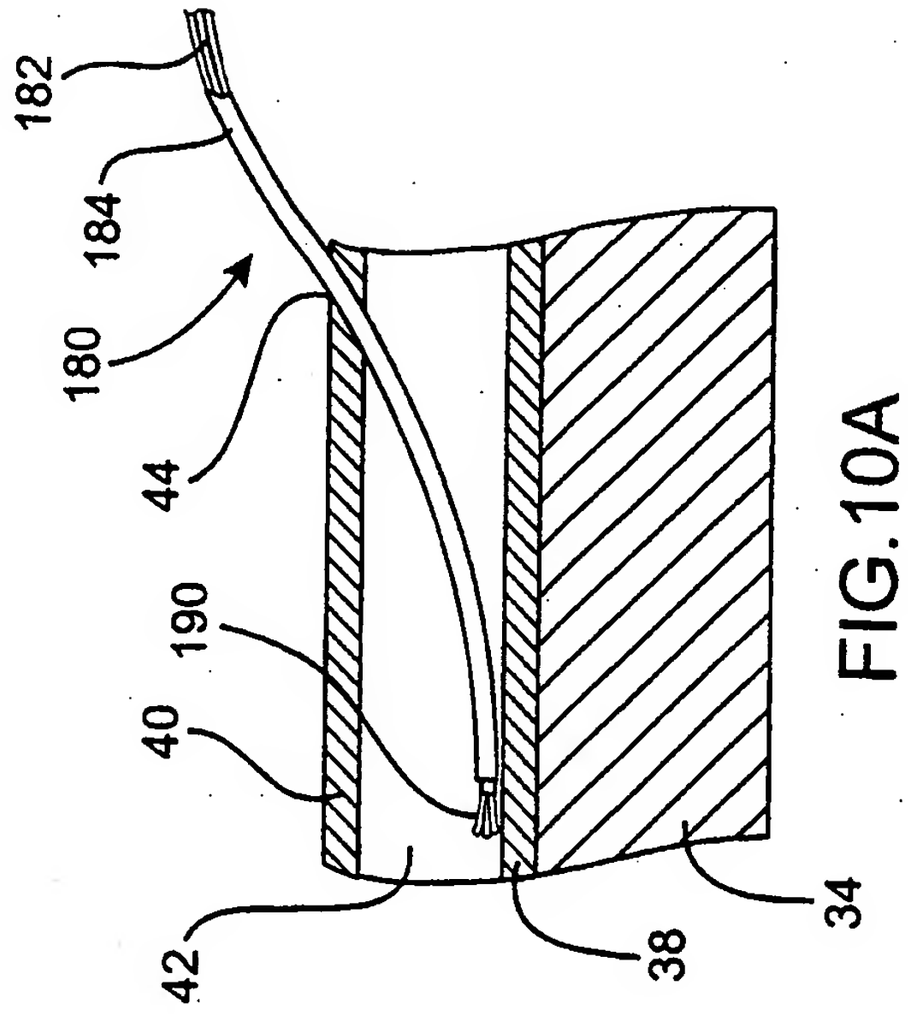


FIG.10A

FIG. 11A

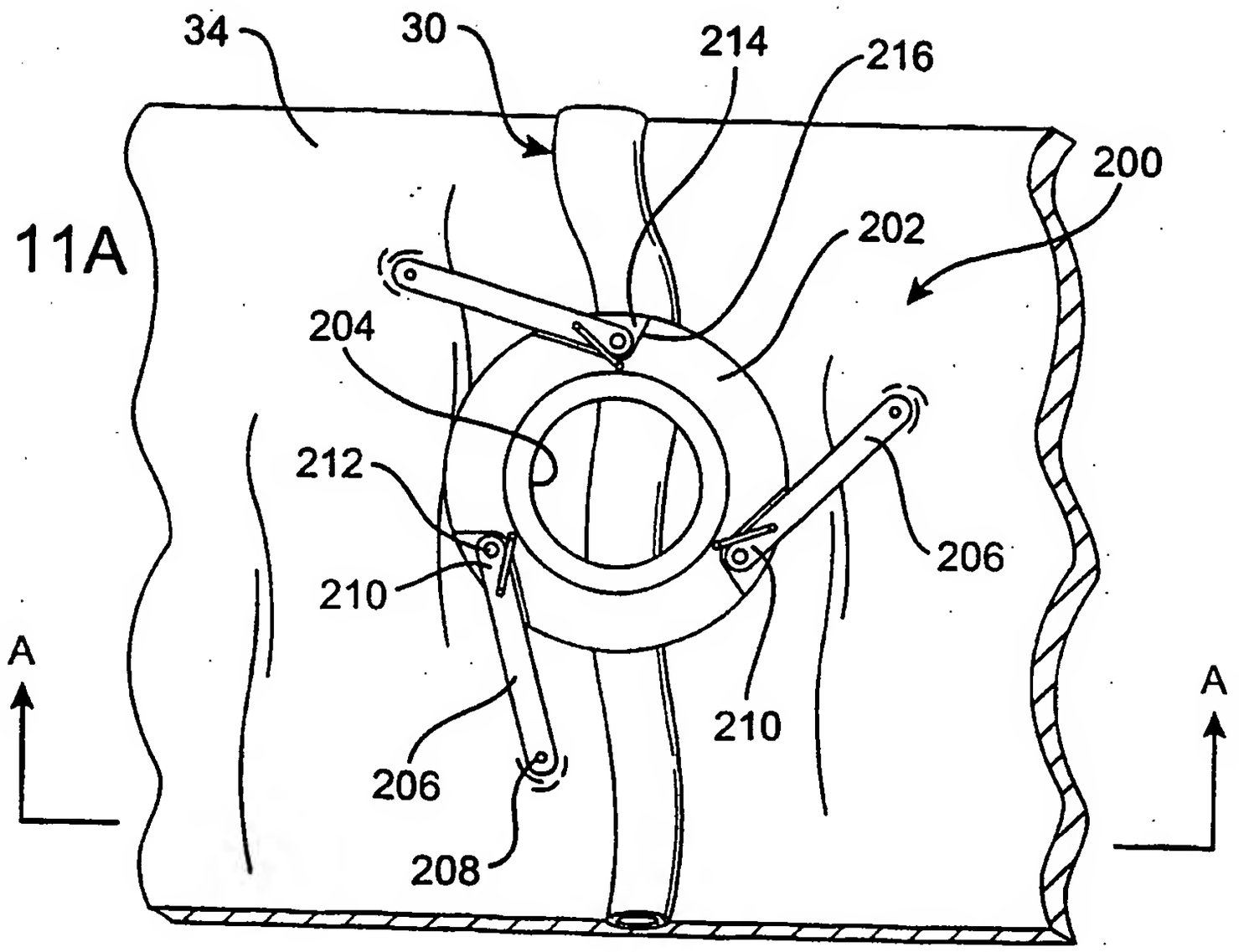


FIG. 11B

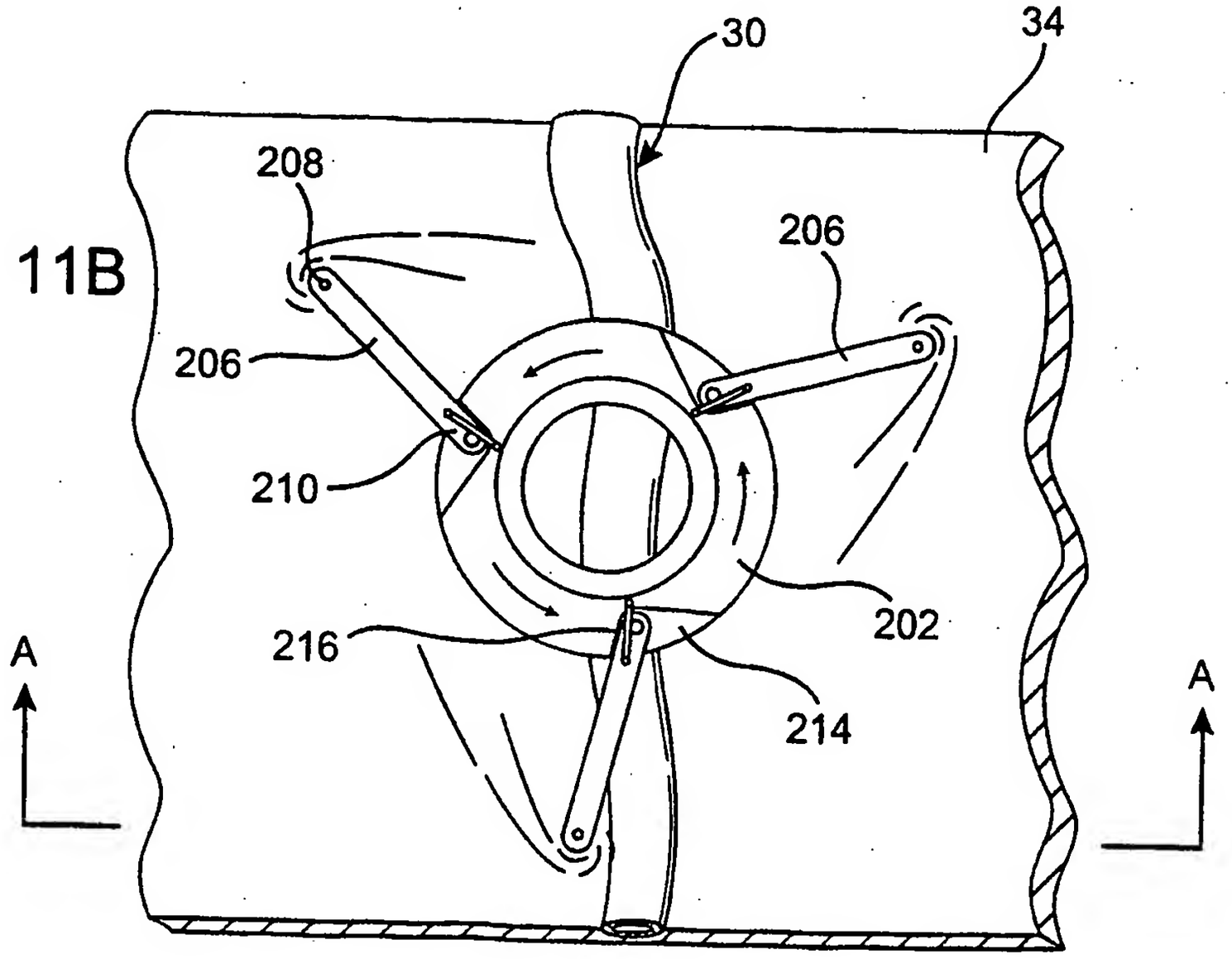


FIG. 12A

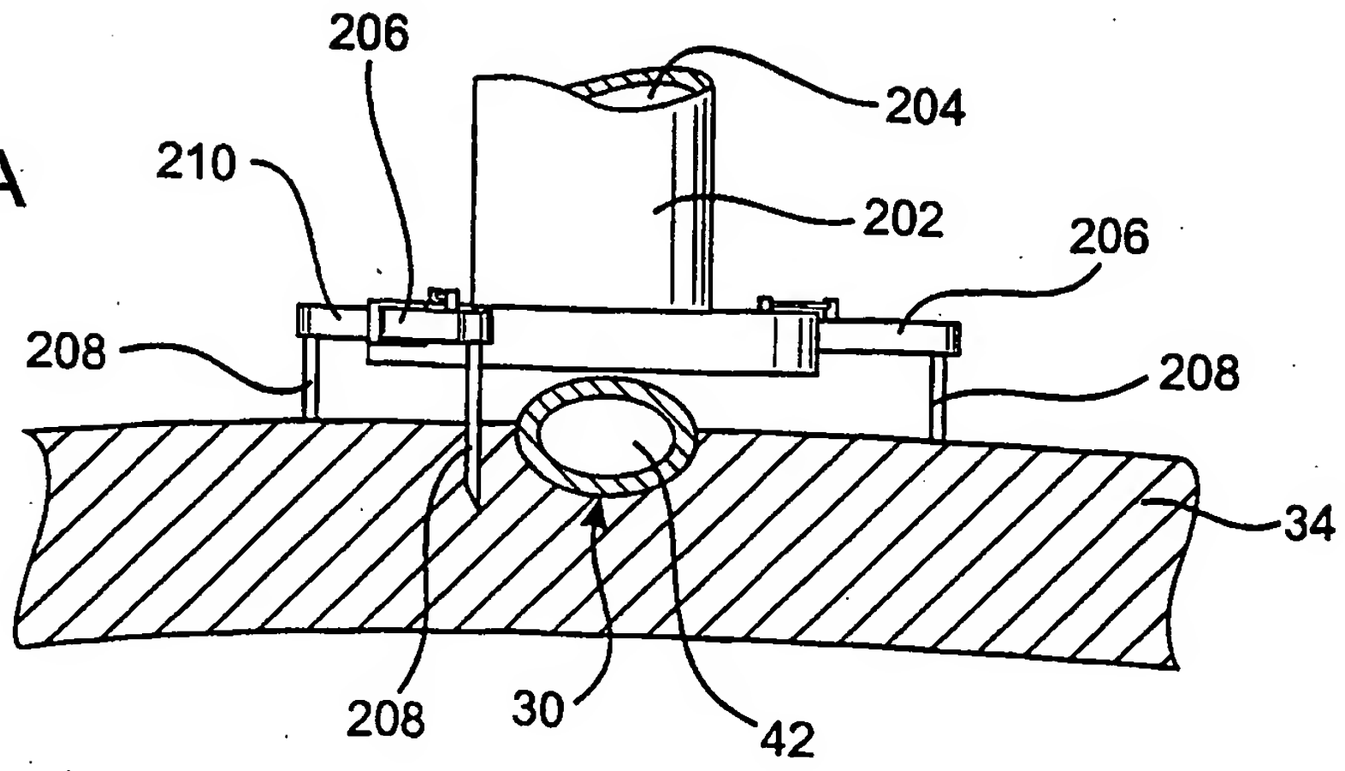


FIG. 12B

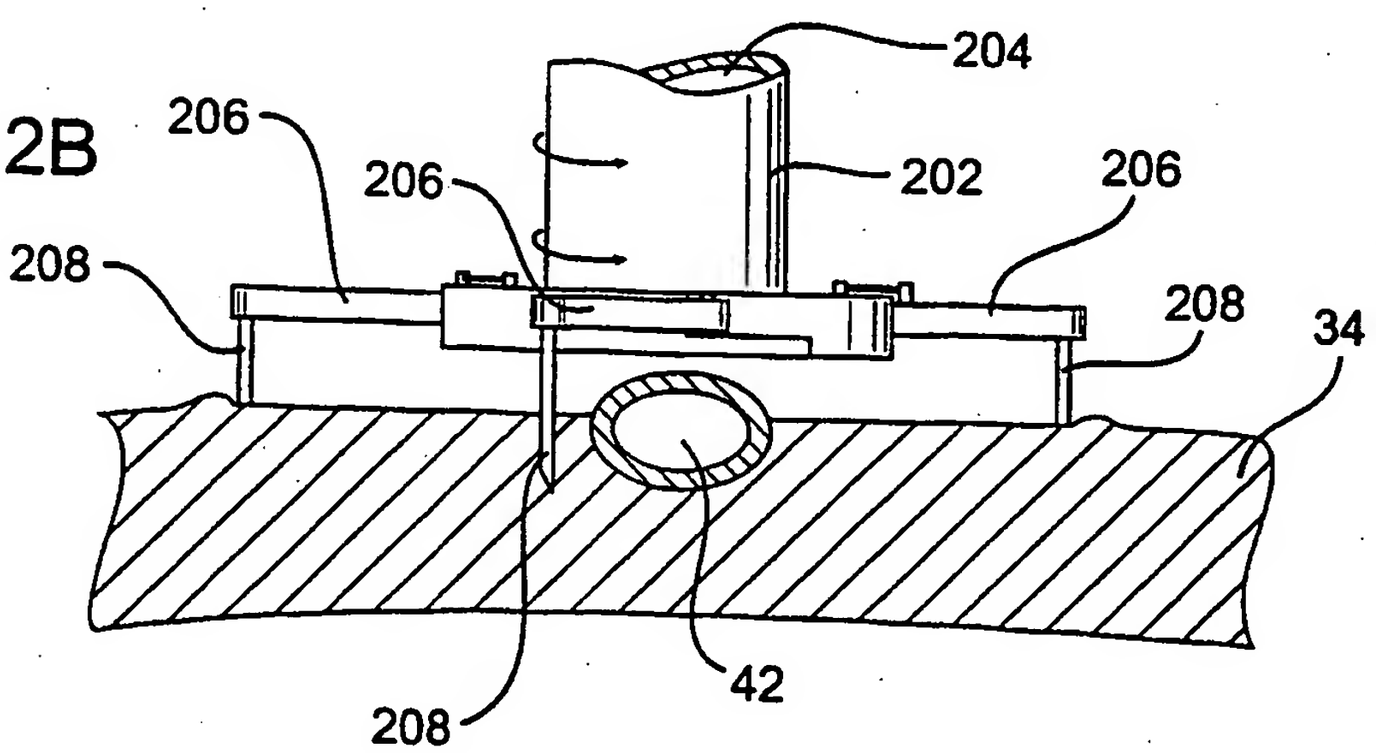


FIG. 13

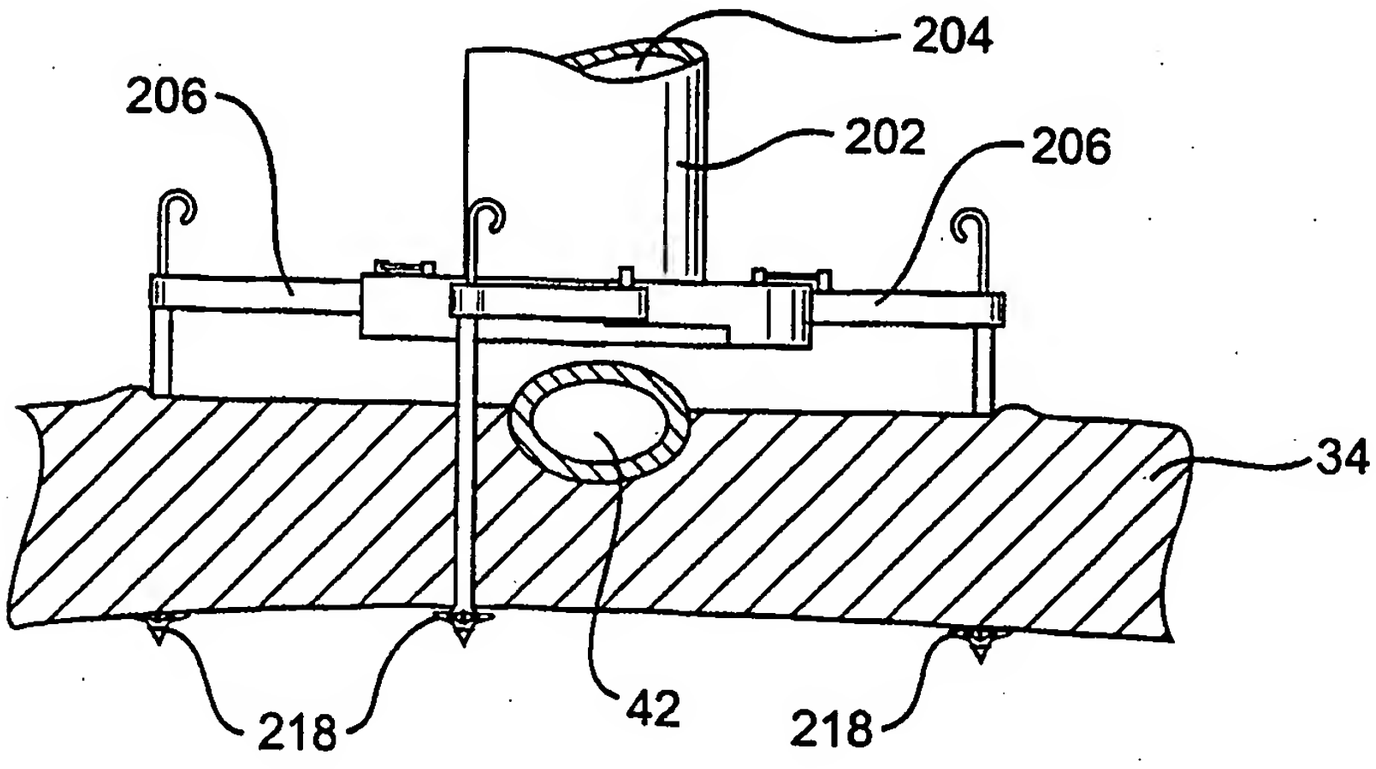


FIG. 14A

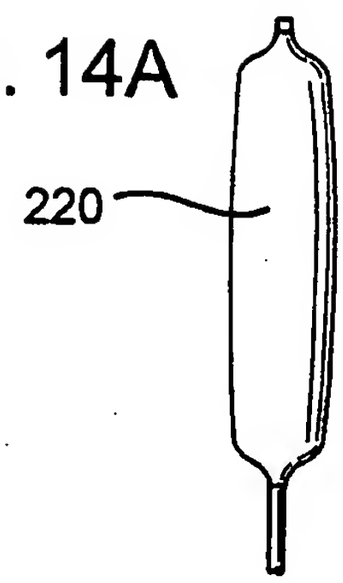


FIG. 14B

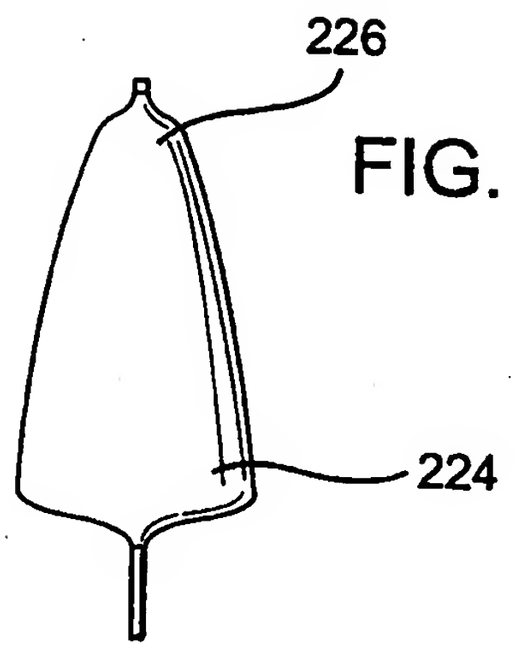


FIG. 15A

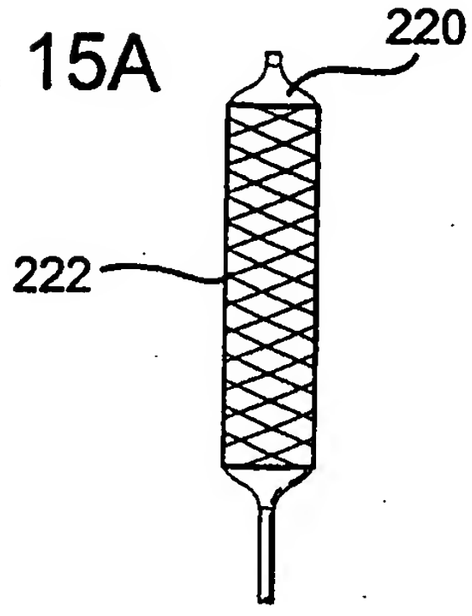
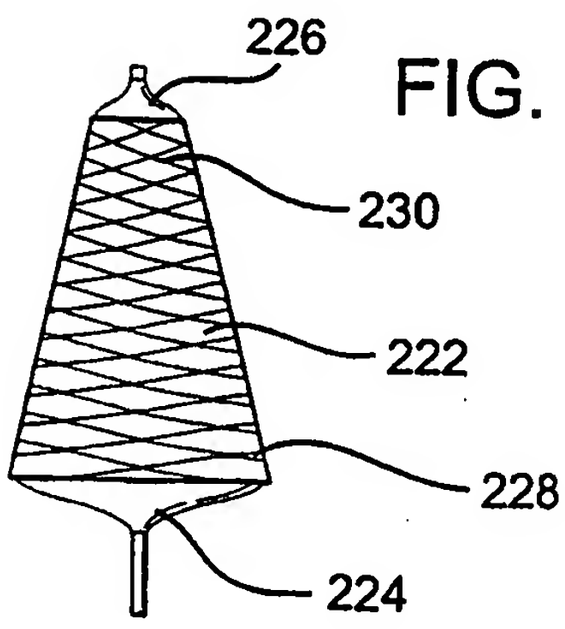


FIG. 15B



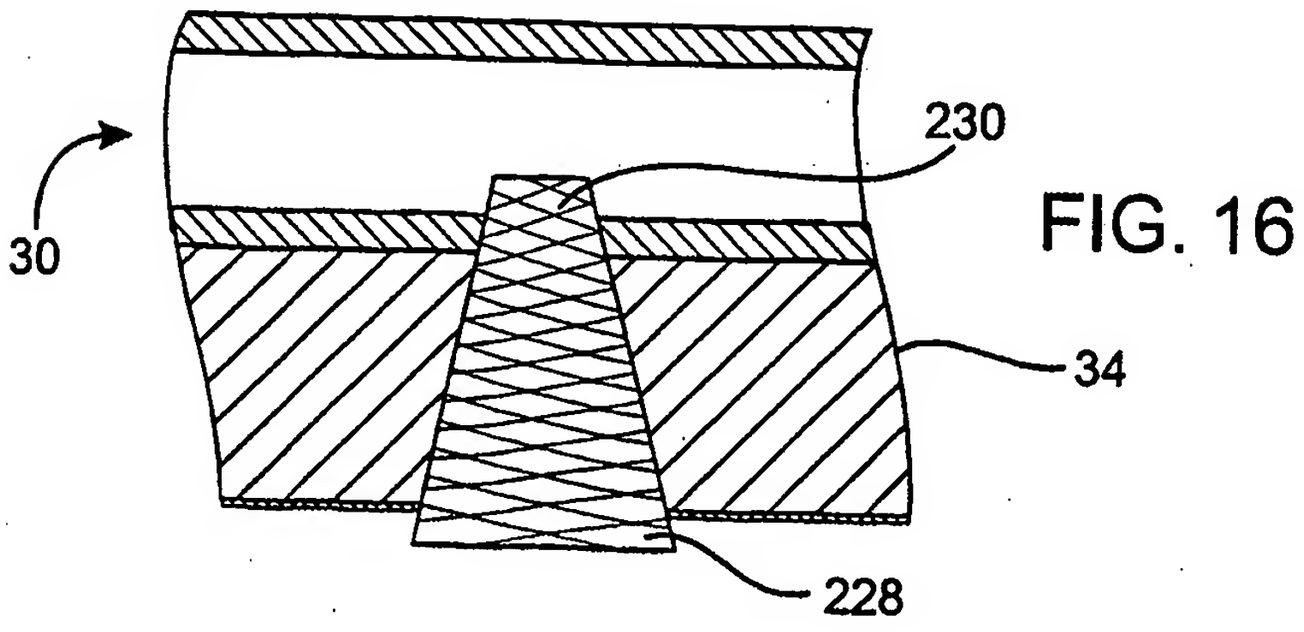


FIG. 16

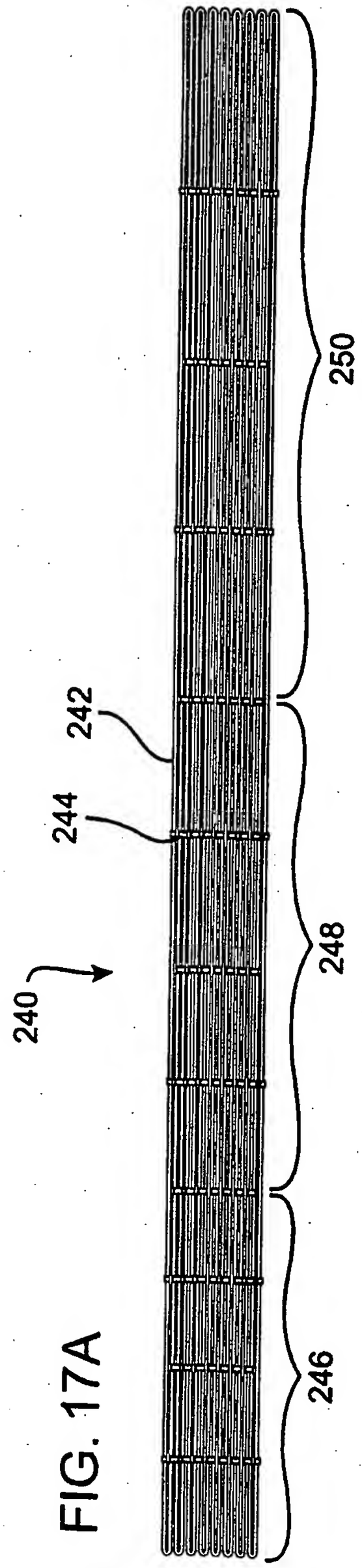


FIG. 17A

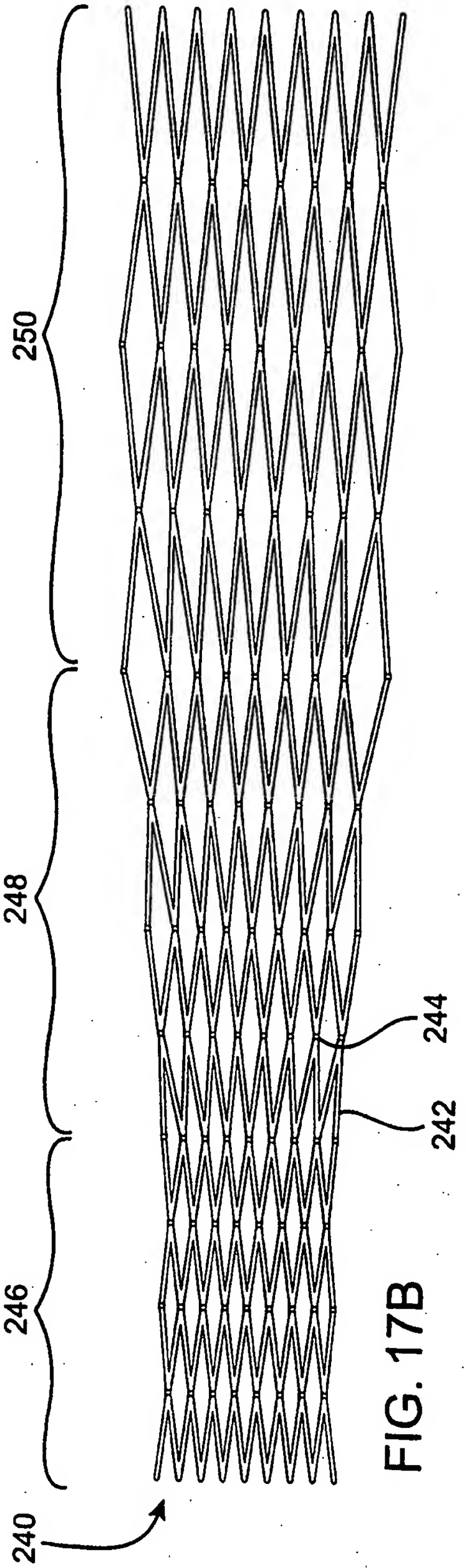


FIG. 17B

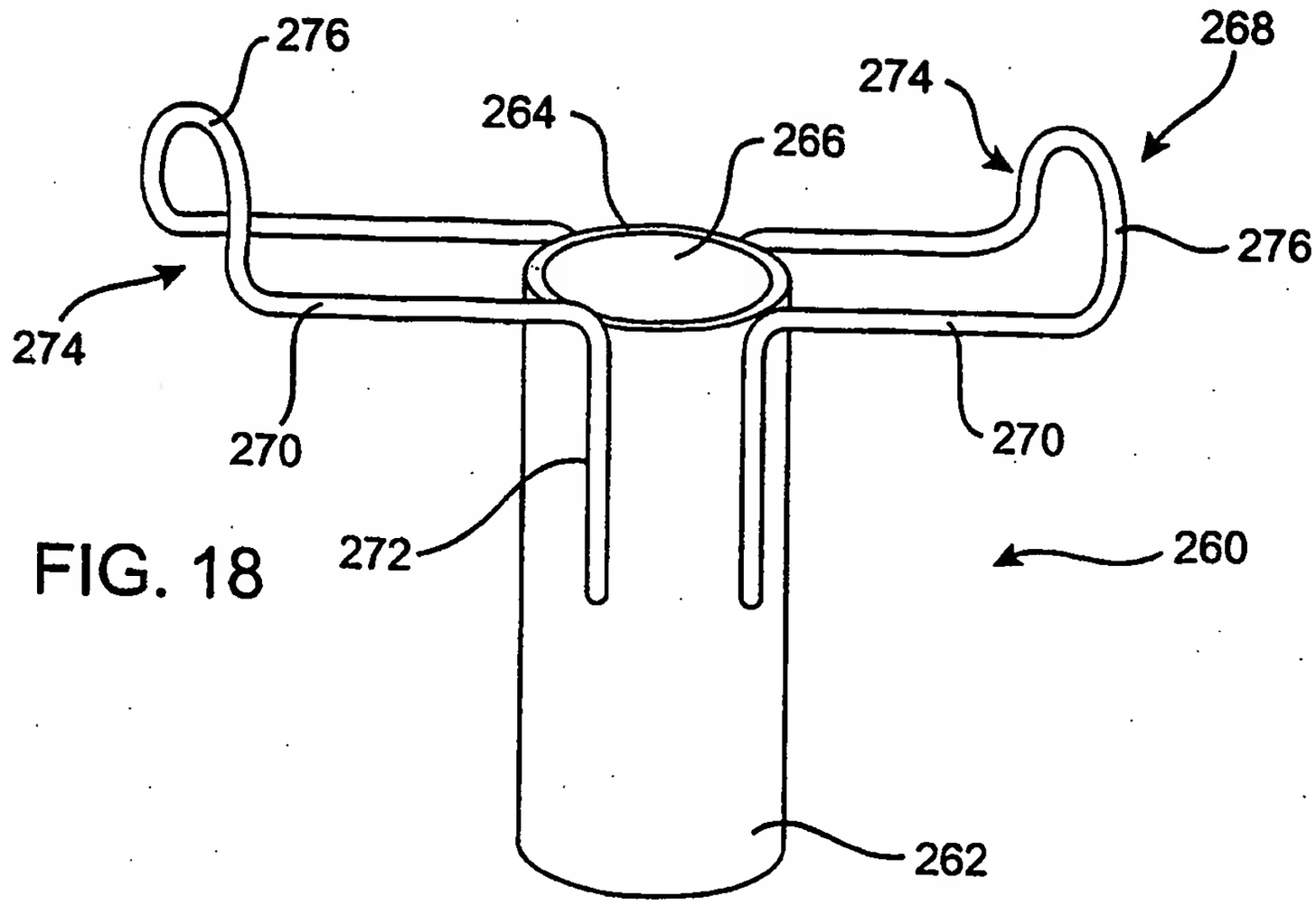


FIG. 18

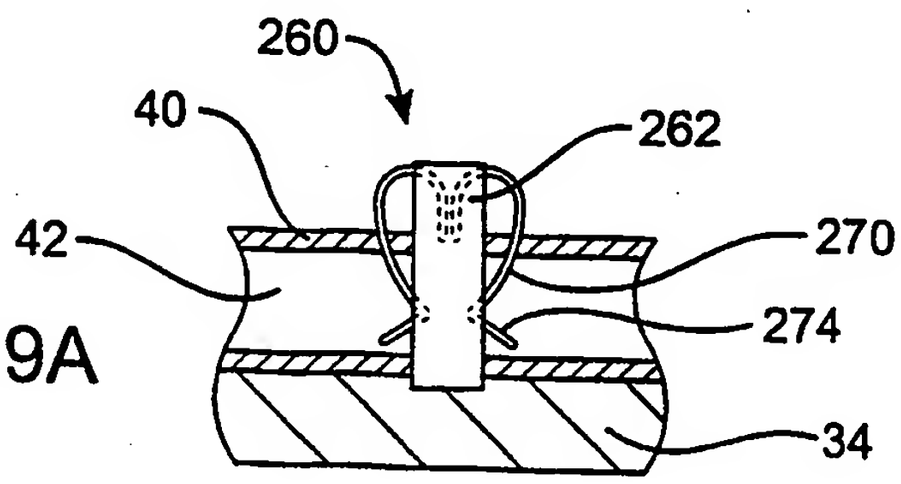


FIG. 19A

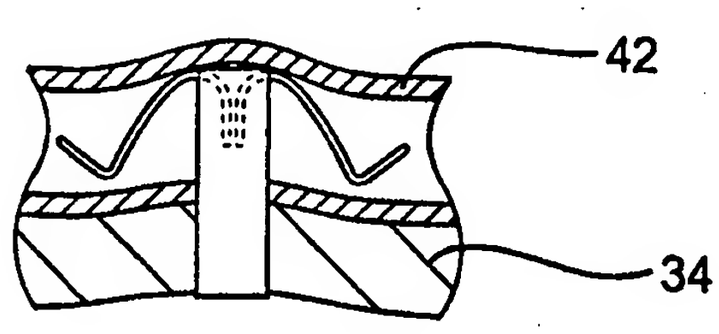


FIG. 19B

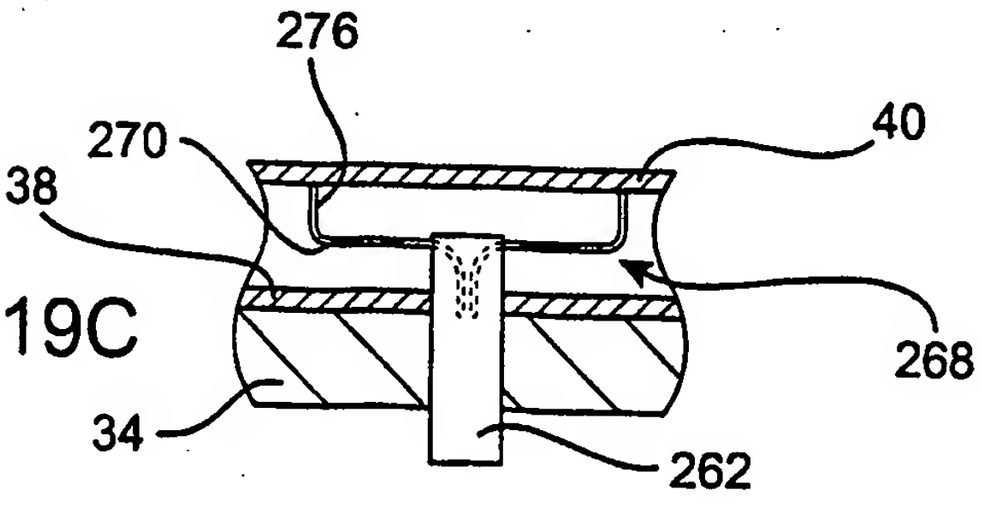
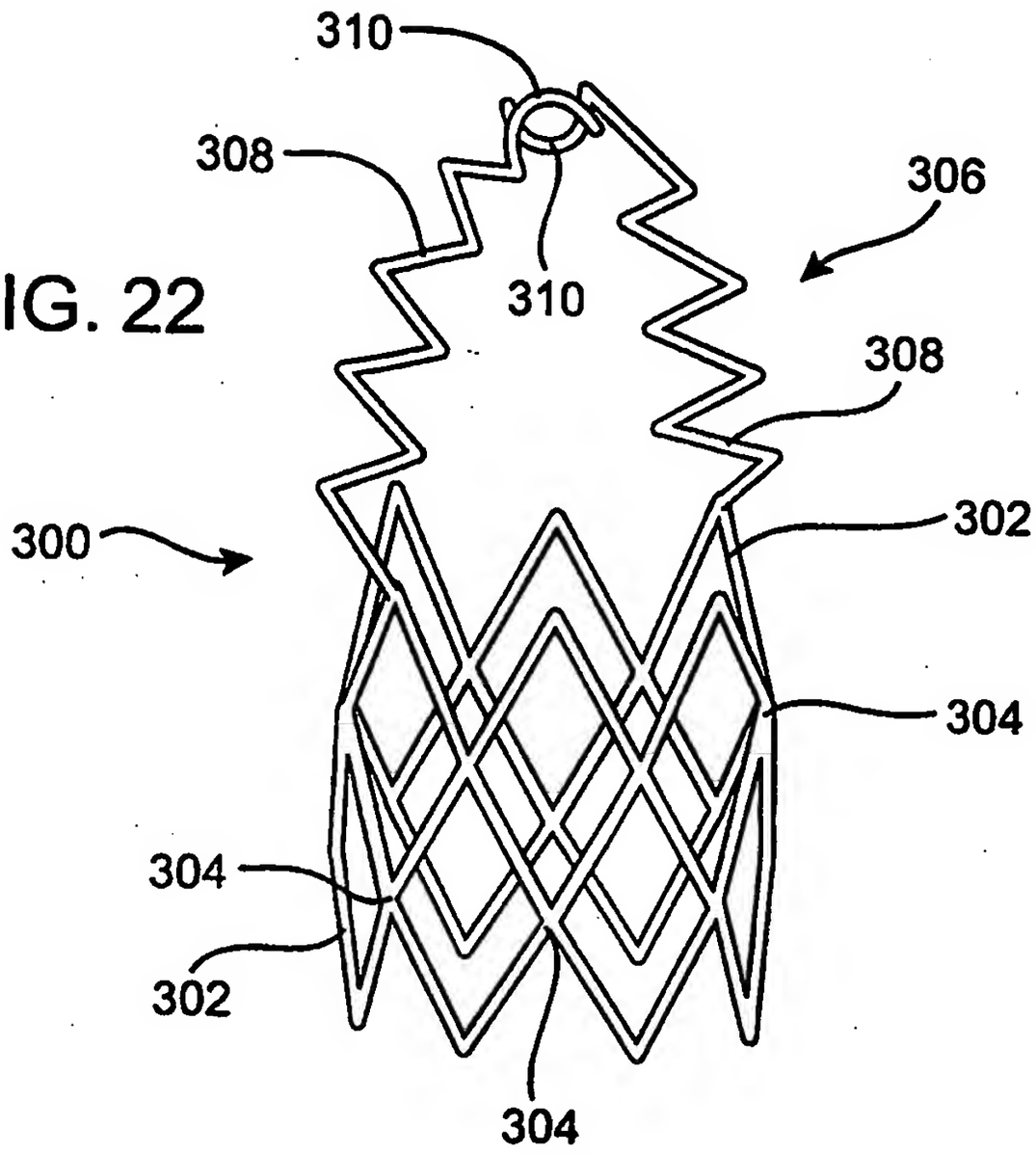


FIG. 19C

FIG. 22



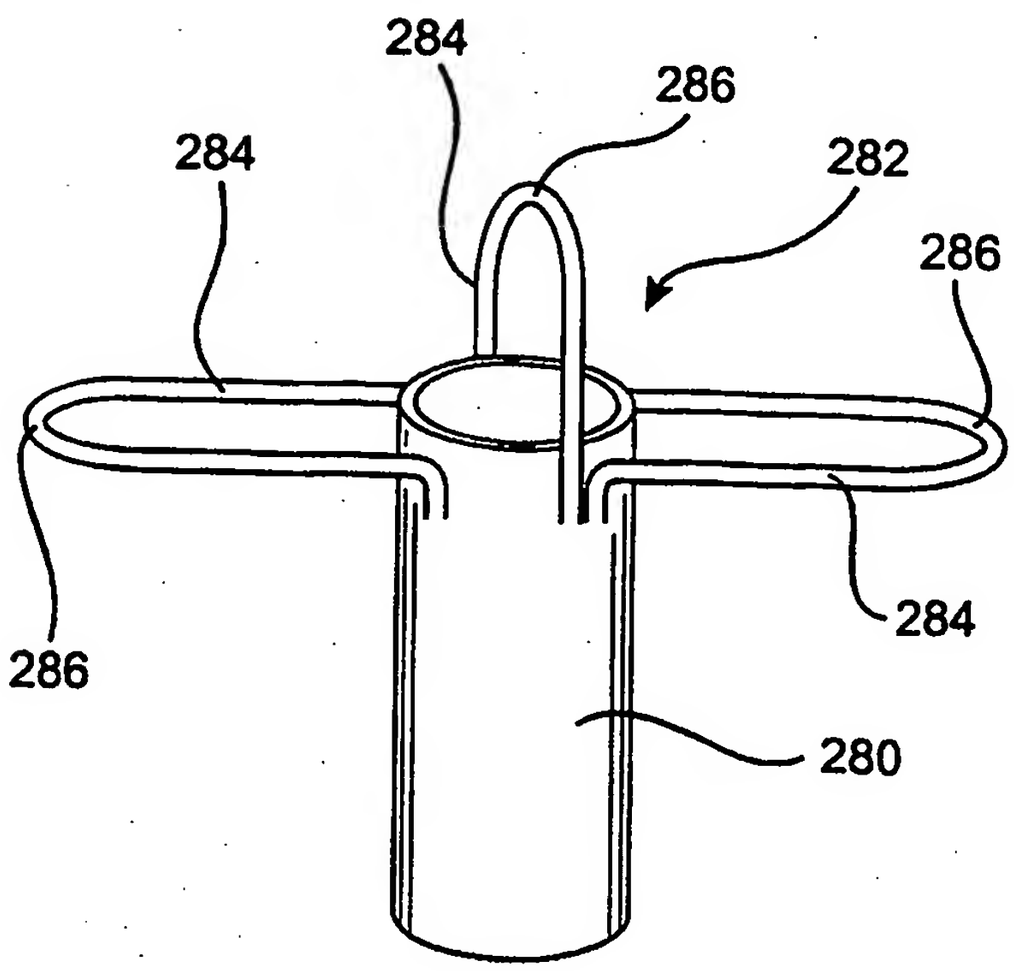


FIG. 20

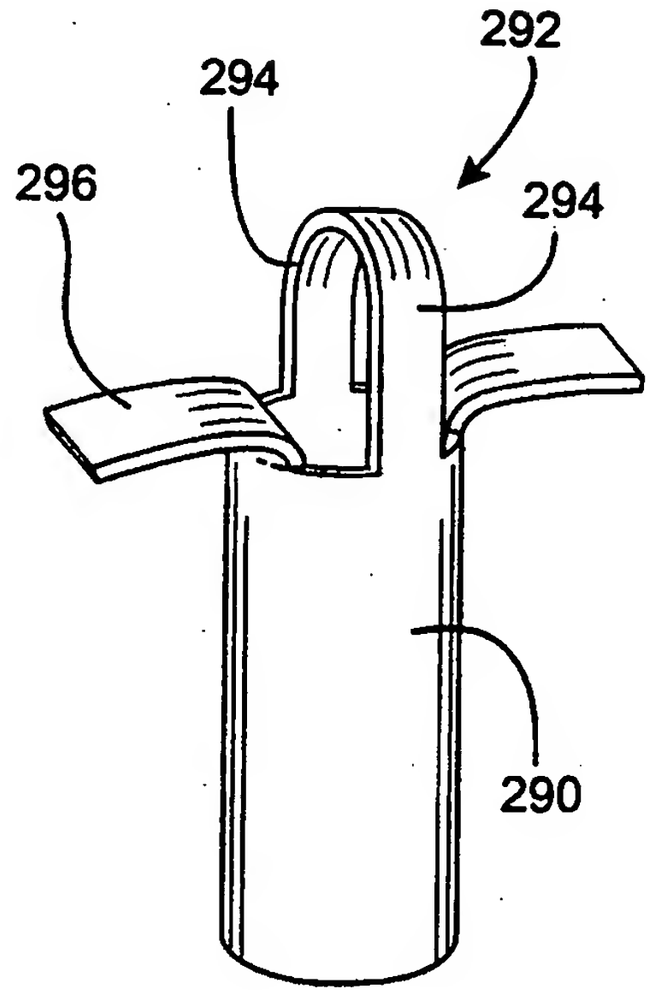


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/22954

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06
US CL :128/898

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/897, 898; 606/191, 194, 195; 623/001, 002

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,922,019 A (HANKH et al.) 13 July 1999, entire document.	1-46
A	US 5,922,022 A (NASH et al.) 13 July 1999, entire document.	1-46
A	US 5,976,178 A (GOLDSTEEN et al.) 02 November 1999, entire document.	1-46
A	US 5,829,447 A (STEVENS et al.) 03 November 1998, entire document.	1-46
Y	US 5,807,243 A (VIERRA et al.) 15 September 1998, entire document.	1-46
Y	US 5,782,746 A (WRIGHT) 21 July 1998, entire document.	1-46

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 JANUARY 2000	29 FEB 2000
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